§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2019–24–15 The Boeing Company: Amendment 39–21004; Docket No. FAA–2019–0980; Product Identifier 2019–NM–180–AD.

(a) Effective Date

This AD is effective January 14, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 737–900ER series airplanes, certificated in any category, as identified in Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a report of nonconforming head strike pads on the mid exit doors. The FAA is issuing this AD to address nonconforming head strike pads which could result in injury to passengers in an otherwise survivable emergency landing and potentially block passenger egress.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Special Attention Service Bulletin 737–25–1831, dated September 24, 2019, which is referred to in Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

(h) Exceptions to Service Information Specifications

Where Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019, uses the phrase ''the original issue date of the Requirements Bulletin 737–25–1831 RB,'' this AD requires using ''the effective date of this AD.''

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

For more information about this AD, contact Allie Buss, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3564; email: *allison.buss@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; phone: 562–797–1717; internet: *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on December 9, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–28070 Filed 12–27–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket Nos. FDA–2017–N–1129 and FDA–2017–N–1610]

Medical Devices; Exemptions From Premarket Notification for Class I and Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) identified a list of class I devices and class II devices that are now exempt from premarket notification requirements, subject to certain limitations. FDA published the lists of final determinations in accordance with procedures established by the 21st Century Cures Act (Cures Act). Although each classification regulation for each such type of device shall be deemed amended to incorporate such exemption, we are publishing this final order to amend the codified language for each listed class I and class II device's classification regulation to reflect the final determinations. FDA's action decreases regulatory burden on the medical device industry and eliminates private costs and expenditures required to comply with certain Federal regulations.

DATES: This order is effective December 30, 2019.

FOR FURTHER INFORMATION CONTACT: Karen Fikes, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5502, Silver Spring, MD 20993, 301–796–9603, email: *karen.fikes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Cures Act (Pub. L. 114–255) was signed into law on December 13, 2016. Under the Cures Act, section 3054 amended section 510(l) and (m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(l) and (m)). As amended, section 510(l)(2) of the FD&C Act requires FDA to identify through publication in the **Federal Register**, any type of class I device that the Agency determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness.

FDA shall publish this determination within 120 days of the date of enactment of the Cures Act and at least once every 5 years thereafter, as FDA determines appropriate. Further, section 510(l)(2) provides that upon the date of publication of the Agency's determination in the **Federal Register**, a 510(k) will no longer be required for these devices and the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

As amended, section 510(m)(1)(A) of the FD&C Act provides that, within 90 days after enactment of the Cures Act and at least once every 5 years thereafter, FDA shall publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. This notice shall provide at least a 60-day comment period. Within 210 days of enactment of the Cures Act, FDA shall publish in the **Federal Register** a list representing its final determination regarding exemption of devices that were contained in the proposed list published under 510(m)(1)(A) of the FD&C Act. Further, section 510(m)(3) of the FD&C Act provides that upon the date of publication of the final list in the **Federal Register**, a 510(k) will no longer be required for these devices and the classification regulation applicable to each such device shall be deemed amended to incorporate such exemption.

In the **Federal Register** of April 13, 2017 (82 FR 17841), in accordance with the amendments to 510(l)(2), FDA issued a notice of final determination to exempt a list of class I devices from premarket notification requirements under section 510(k) of the FD&C Act, subject to certain limitations. In the **Federal Register** of March 14, 2017 (82 FR 13609), in accordance with the amendments to 510(m)(1)(A), FDA issued a notice proposing to exempt a list of class II devices from premarket notification requirements under section 510(k) of the FD&C Act, subject to certain limitations. After a 60-day comment period, in the **Federal Register** of July 11, 2017 (82 FR 31976), FDA issued a notice of final determination to exempt class II devices provided in the proposed list. Through this action, FDA is now amending the codified language for each listed classification regulation to reflect final determinations for these class I and class II exemptions.[1]

Following publication of the notices, FDA determined that it is unnecessary to update three classification regulations (21 CFR 872.4565, 21 CFR 878.4014, and 21 CFR 880.6320) included in the class I notice, 82 FR 17841. Five product codes corresponding to these three classification regulations (EGI and EIB (21 CFR 872.4565), OVR (21 CFR 878.4014), KZF and PEQ (21 CFR 880.6320)) were identified for exemption in 82 FR 17841; however, the corresponding classification regulations were already class I, exempt from premarket notification procedures in subpart E of part 807 (21 CFR part 807, subpart E) subject to the limitations in the corresponding ''.9'' regulations (*i.e.,* 21 CFR 872.9, 21 CFR 878.9 or 21 CFR 880.9); and, therefore, no revisions to the codified are necessary. Additionally, we determined that it is unnecessary to update 21 CFR 876.5820 included in the class II notice, 82 FR 13609. The product code within this classification regulation (FKI) was identified for exemption in 82 FR 13609. However, this device type is specifically identified within the class I paragraph of this classification regulation (21 CFR 876.5820(b)(2)) and already exempt from premarket notification procedures in subpart E of part 807 subject to the limitations in 21 CFR 876.9. Therefore, no revisions to the codified are necessary.

We are also making a revision to correct a misidentified classification regulation in 82 FR 31976. The notice incorrectly listed the classification regulation 21 CFR 868.1400 ''Carbon dioxide gas analyzer'' as corresponding with product code LLK; however, the correct classification regulation associated with product code LLK is 21 CFR 880.5780 ''Medical Support Stocking''. Therefore, 21 CFR 868.1400 remains unchanged, and 21 CFR 880.5780(a)(2) is revised to reflect the exemption.

We are revising the name of one classification regulation, currently entitled ''Urological clamp for males'', in response to FDA's exemption in 82 FR 17841. Part 876.5160 is currently entitled ''Urological clamp for males,'' which was previously exempt from premarket notification procedures ''. . . Except when intended for internal use or use on females . . .''. In 82 FR 17841, we exempted product code MNG, ''External Urethral Occluder, Urinary Incontinence-Control, Female'' and removed the current limitation language regarding ''use on females.'' Therefore, FDA is revising the name of the classification regulation to read ''Urological clamp'' to ensure clarity.

II. Criteria for Exemption

As amended by the Cures Act, section 510(l) now has two provisions, 510(l)(1) and (2). Under 510(1)(1), a class I device is exempt from the premarket notification requirements under section 510(k) of the FD&C Act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. Based on these criteria, FDA evaluated all class I devices to determine which device types should be exempt from premarket notification requirements.

For class II devices, there are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance we issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff''.[2]

III. Limitations on Exemptions

Although FDA exempted the types of class I and class II devices from the premarket notification requirements under section 510(k) of the FD&C Act in accordance with the provisions under 510(l) and (m), an exemption from the requirement of premarket notification does not mean the device is exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation. FDA's determination that premarket notification is unnecessary to provide a reasonable assurance of safety and effectiveness is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements, provide.

In addition to being subject to the general limitations to the exemptions found in 21 CFR 862.9 to 892.9, FDA has also partially limited some exemptions from premarket notification requirements to specific devices within

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

[2] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff.*

the listed device type. In such situations where a partial exemption limitation has been identified, FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for these devices.

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This final order refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073.

List of Subjects

21 CFR Parts 862, 868, 870, 872, 874, 876, 878, 880, 882, 884, 888, and 890

Medical devices.

21 CFR Part 864

Blood, Medical devices, Packaging and Containers.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892 are amended as follow:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. In § 862.1020, revise paragraph (b) to read as follows:

§ 862.1020 Acid phosphatase (total or prostatic) test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 3. In § 862.1090, revise paragraph (b) to read as follows:

§ 862.1090 Angiotensin converting enzyme (A.C.E.) test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 4. In § 862.1100, revise paragraph (b) to read as follows:

§ 862.1100 Aspartate amino transferase (AST/SGOT) test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 5. In § 862.1150, revise paragraph (b) to read as follows:

§ 862.1150 Calibrator.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 6. In § 862.1345, revise paragraph (b) to read as follows:

§ 862.1345 Glucose test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 7. In § 862.1350, revise paragraph (b) introductory text to read as follows:

§ 862.1350 Continuous glucose monitor secondary display.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9. The special controls for this device are:

* * * * *

■ 8. In § 862.1410, revise paragraph (b) to read as follows:

§ 862.1410 Iron (non-heme) test system.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 9. In § 862.1415, revise paragraph (b) to read as follows:

§ 862.1415 Iron-binding capacity test system.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 10. In § 862.1445, revise paragraph (b) to read as follows:

§ 862.1445 Lactate dehydrogenase isoenzymes test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 11. In § 862.1509, revise paragraph (b) to read as follows:

§ 862.1509 Methylmalonic acid (nonquantitative) test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 12. In § 862.1580, revise paragraph (b) to read as follows:

§ 862.1580 Phosphorous (inorganic) test system.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 13. In § 862.1660, revise paragraph (b) to read as follows:

§ 862.1660 Quality control material (assayed and unassayed).

* * * * *

(b) *Classification.* Class I (general controls). Except when intended for use in donor screening tests, quality control materials (assayed and unassayed) are

exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 14. In § 862.1685, revise paragraph (b) as follows:

§ 862.1685 Thyroxine-binding globulin test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 15. In § 862.1700, revise paragraph (b) as follows:

§ 862.1700 Total thyroxine test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 16. In § 862.1775, revise paragraph (b) to read as follows:

§ 862.1775 Uric acid test system.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 17. In § 862.2265, revise paragraph (b) introductory text to read as follows:

§ 862.2265 High throughput genomic sequence analyzer for clinical use.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9. The special controls for this device are:

* * * * *

■ 18. In § 862.2570, revise paragraph (b) to read as follows:

§ 862.2570 Instrumentation for clinical multiplex test systems.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9. The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems.'' See § 862.1(d) for the availability of this guidance document.

■ 19. In § 862.3050, revise paragraph (b) to read as follows:

§ 862.3050 Breath-alcohol test system.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 20. In § 862.3100, revise paragraph (b) to read as follows:

§ 862.3100 Amphetamine test system.

* * * * *

(b) *Classification.* Class II (special controls). An amphetamine test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 21. In § 862.3150, revise paragraph (b) to read as follows:

§ 862.3150 Barbiturate test system.

* * * * *

(b) *Classification.* Class II (special controls). A barbiturate test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 22. In § 862.3170, revise paragraph (b) to read as follows:

§ 862.3170 Benzodiazepine test system.

* * * * *

(b) *Classification.* Class II (special controls). A benzodiazepine test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 23. In § 862.3200, revise paragraph (b) to read as follows:

§ 862.3200 Clinical toxicology calibrator.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 24. In § 862.3220, revise paragraph (b) to read as follows:

§ 862.3220 Carbon monoxide test system.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 25. In § 862.3240, revise paragraph (b) to read as follows:

§ 862.3240 Cholinesterase test system.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 26. In § 862.3250, revise paragraph (b) to read as follows:

§ 862.3250 Cocaine and cocaine metabolite test system.

* * * * *

(b) *Classification.* Class II (special controls). A cocaine and cocaine metabolite test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,*

programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 27. In § 862.3270, revise paragraph (b) to read as follows:

§ 862.3270 Codeine test system.

* * * * *

(b) *Classification.* Class II (special controls). A codeine test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 28. In § 862.3280, revise paragraph (b) to read as follows:

§ 862.3280 Clinical toxicology control material.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 29. In § 862.3580, revise paragraph (b) to read as follows:

§ 862.3580 Lysergic acid diethylamide (LSD) test system.

* * * * *

(b) *Classification.* Class II (special controls). A lysergic acid diethylamide (LSD) test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 30. In § 862.3610, revise paragraph (b) to read as follows:

§ 862.3610 Methamphetamine test system.

* * * * *

(b) *Classification.* Class II (special controls). A methamphetamine test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 31. In § 862.3620, revise paragraph (b) to read as follows:

§ 862.3620 Methadone test system.

* * * * *

(b) *Classification.* Class II (special controls). A methadone test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 32. In § 862.3630, revise paragraph (b) to read as follows:

§ 862.3630 Methaqualone test system.

* * * * *

(b) *Classification.* Class II (special controls). A methaqualone test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 33. In § 862.3640, revise paragraph (b) to read as follows:

§ 862.3640 Morphine test system.

* * * * *

(b) *Classification.* Class II (special controls). A morphine test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 34. In § 862.3650, revise paragraph (b) to read as follows:

§ 862.3650 Opiate test system.

* * * * *

(b) *Classification.* Class II (special controls). An opiate test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 35. In § 862.3700, revise paragraph (b) to read as follows:

§ 862.3700 Propoxyphene test system.

* * * * *

(b) *Classification.* Class II (special controls). A propoxyphene test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 36. In § 862.3870, revise paragraph (b) to read as follows:

§ 862.3870 Cannabinoid test system.

* * * * *

(b) *Classification.* Class II (special controls). A cannabinoid test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 37. In § 862.3910, revise paragraph (b) to read as follows:

§ 862.3910 Tricyclic antidepressant drugs test system.

* * * * *

(b) *Classification.* Class II (special controls). A tricyclic antidepressant drugs test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 38. The authority citation for part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 39. In § 864.5400, revise paragraph (b) to read as follows:

§ 864.5400 Coagulation instrument.

* * * * *

(b) *Classification.* Class II (special controls). A fibrometer or coagulation timer intended for use with a coagulation instrument is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 40. In § 864.5425, revise paragraph (b) to read as follows:

§ 864.5425 Multipurpose system for in vitro coagulation studies.

* * * * *

(b) *Classification.* Class II (special controls). A control intended for use with a multipurpose system for in vitro coagulation studies is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 41. In § 864.6550, revise paragraph (b) to read as follows:

§ 864.6550 Occult blood test.

* * * * *

(b) *Classification.* Class II (special controls). A control intended for use with an occult blood test is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 42. In § 864.7040, revise paragraph (b) to read as follows:

§ 864.7040 Adenosine triphosphate release assay.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 43. In § 864.7275, revise paragraph (b) to read as follows:

§ 864.7275 Euglobulin lysis time tests.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 44. In § 864.7300, revise paragraph (b) to read as follows:

§ 864.7300 Fibrin monomer paracoagulation test.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. The special control for this device is FDA's ''In Vitro Diagnostic Fibrin Monomer Paracoagulation Test.'' See § 864.1(d) for information on obtaining this document.

■ 45. In § 864.7340, revise paragraph (b) to read as follows:

§ 864.7340 Fibrinogen determination system.

* * * * *

(b) *Classification.* Class II (special controls). A control or fibrinogen standard intended for use with a fibrinogen determination system is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 46. In § 864.7375, revise paragraph (b) to read as follows:

§ 864.7375 Glutathione reductase assay.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 47. In § 864.7415, revise paragraph (b) to read as follows:

§ 864.7415 Abnormal hemoglobin assay.

* * * * *

(b) *Classification.* Class II (special controls). A control intended for use with an abnormal hemoglobin assay is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 48. In § 864.7455, revise paragraph (b) to read as follows:

§ 864.7455 Fetal hemoglobin assay.

* * * * *

(b) *Classification.* Class II (special controls). A fetal hemoglobin stain intended for use with a fetal hemoglobin assay is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 49. In § 864.7500, revise paragraph (b) to read as follows:

§ 864.7500 Whole blood hemoglobin assays.

* * * * *

(b) *Classification.* Class II (special controls). An acid hematin intended for use with whole blood hemoglobin assays is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 50. In § 864.7720, revise paragraph (b) to read as follows:

§ 864.7720 Prothrombin consumption test.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 51. In § 864.7735, revise paragraph (b) to read as follows:

§ 864.7735 Prothrombin-proconvertin test and thrombotest.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 52. In § 864.8150, revise paragraph (b) to read as follows:

§ 864.8150 Calibrator for cell indices.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 53. In § 864.8165, revise paragraph (b) to read as follows:

§ 864.8165 Calibrator for hemoglobin or hematocrit measurement.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 54. In § 864.8175, revise paragraph (b) to read as follows:

§ 864.8175 Calibrator for platelet counting.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 55. In § 864.8185, revise paragraph (b) to read as follows:

§ 864.8185 Calibrator for red cell and white cell counting.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 56. In § 864.8625, revise paragraph (b) to read as follows:

§ 864.8625 Hematology quality control mixture.

* * * * *

(b) *Classification.* Class II (special controls). Except when intended for use in blood components, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 57. In § 864.9400, revise paragraph (b) to read as follows:

§ 864.9400 Stabilized enzyme solution.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 58. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 59. In § 866.2900, revise paragraph (b) to read as follows:

§ 866.2900 Microbiological specimen collection and transport device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

■ 60. In § 866.3395, revise paragraph (b) to read as follows:

§ 866.3395 Norovirus serological reagents.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Norovirus Serological Reagents.'' See § 866.1(e) for the availability of this guidance document.

■ 61. In § 866.5210, revise paragraph (b) to read as follows:

§ 866.5210 Ceruloplasmin immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

■ 62. In § 866.5470, revise paragraph (b) to read as follows:

§ 866.5470 Hemoglobin immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

■ 63. In § 866.5620, revise paragraph (b) to read as follows:

§ 866.5620 *Alpha*-2-macroglobulin immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

■ 64. In § 866.5630, revise paragraph (b) to read as follows:

§ 866.5630 *Beta*-2-microglobulin immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

■ 65. In § 866.5750, revise paragraph (b) to read as follows:

§ 866.5750 Radioallergosorbent (RAST) immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device, when intended to detect any of the allergens included in Table 1 in this paragraph, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS

Allergen code	Allergen product	Source (taxonomical name)
	Grass Pollens	
g1	Sweet vernal grass	*Anthoxanthum odoratum.*
g3	Cocksfoot grass, Orchard grass	*Dactylis glomerata.*
g4	Meadow fescue	*Festuca elatior.*
g5	Rye-grass (perennial rye grass)	*Lolium perenne.*
g7	Common reed (common reed grass)	*Phragmites communis.*
g8	Meadow grass, Kentucky blue (June grass)	*Poa pratensis.*
g9	Redtop, Bentgrass	*Agrostis stolonifera*, *Agrostis gigantea* (*Agrostis alba*).
g11	Brome grass	*Bromus inermis.*
g12	Cultivated rye (cultivated rye grass)	*Secale cereale.*
g13	Velvet grass	*Holcus lanatus.*
g14	Cultivated oat (cultivated oat grass)	*Avena sativa.*
g15	Cultivated wheat (cultivated wheat grass)	*Triticum aestivum* (*Triticum* spp.).
g16	Meadow foxtail (meadow foxtail grass)	*Alopecurus pratensis.*
g17	Bahia grass	*Paspalum notatum.*
g24	Wheat grass, Western	*Agropyron smithii* (*Elymus smithii*).
g30	Bluegrass, annual	*Poa annua.*
g70	Wild rye grass	*Elymus triticoides Elymus condensatus.*
g71	Canary grass	*Phalaris arundinacea.*
g201	Barley, cultivated	*Hordeum vulgare.*
g202	Maize, corn (cultivated corn)	*Zea mays.*
g203	Salt grass	*Distichlis spicata.*
g204	False oat-grass	*Arrhenatherum elatius.*
g216	Cyn d 1	*Cynodon dactylon.*
g701	Phl p 1.0102, Phl p 5.0101	*Phleum pratense.*
g702	Phl p 7.0101	*Phleum pratense.*
g703	Phl p 12.0101	*Phleum pratense.*
	Weed Pollens	
w2	Western ragweed	*Ambrosia psilostachya.*
w4	False ragweed	*Ambrosia acanthicarpa* (*Franseria acanthicarpa*).
w5	Wormwood	*Artemisia absinthium Artemisia annua.*
w6	Mugwort	*Artemisia vulgaris.*
w7	Marguerite, ox-eye daisy	*Chrysanthemum leucanthemum.*
w8	Dandelion	*Taraxacum vulgare*, *Taraxacum officinale.*
w9	Plantain (English), Ribwort	*Plantago lanceolata.*
w10	Goosefoot, lamb's quarters	*Chenopodium album.*
w11	Saltwort (prickly), Russian thistle	*Salsola kali* (*Salsola pestifer*).
w12	Goldenrod	*Solidago virgaurea* (*Solidago* spp.).
w13	Cocklebur, common	*Xanthium commune.*
w14	Common pigweed (rough pigweed)	*Amaranthus retroflexus.*
w15	Scale, Lenscale	*Atriplex lentiformis.*
w16	Rough marsh elder	*Iva ciliate*, *Iva annua.*
w17	Firebush (Kochia)	*Kochia scoparia.*
w18	Sheep sorrel	*Rumex acetosella.*
w19	Wall pellitory	*Parietaria officinalis.*
w20	Nettle (Common stinging nettle)	*Urtica dioica.*
w21	Wall pellitory	*Parietaria judaica.*
w22	Japanese hop (careless weed)	*Humulus japonicas* (*Humulus scandens*).
w23	Yellow dock, Yellow dockweed	*Rumex crispus.*
w24	Spiny pigweed	*Amaranthus spinosus.*
w27	Carnation	*Dianthus* spp.
w28	Rose	*Rosa rugosa.*
w33	Clover	*Trifolium pratense.*
w35	Mexican tea	*Chenopodium ambrosioides.*
w36	Rabbit bush	*Ambrosia deltoidea* (*Franseria deltoides*).
w37	Salt bush, annual	*Atriplex wrightii.*
w39	Water hemp, Western	*Amaranthus rudis* (*Acnida tamariscina*).
w41	Burrobrush	*Hymenoclea salsola.*
w42	Poverty weed	*Baccharis neglecta.*
w43	Common sagebrush	*Artemisia tridentata.*
w45	Alfalfa	*Medicago sativa.*
w46	Dog fennel	*Eupatorium capillifolium.*
w53	Geranium	*Geranium* spp.
w67	Groundsel bush	*Baccharis halimifolia.*
w69	Iodine bush	*Allenrolfea occidentalis.*
w70	Ragweed, slender	*Ambrosia confertiflora.*
w75	Wing scale (wingscale)	*Atriplex canescens.*

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

Allergen code	Allergen product	Source (taxonomical name)
w82	Careless weed	*Amaranthus palmeri*, *Amaranthus hybridus.*
w90	Japanese hop	*Humulus japonicas* (*Humulus scandens*).
w203	Rape (rape pollen)	*Brassica napus.*
w204	Sunflower	*Helianthus annuus.*
w206	Camomile	*Matricaria chamomilla.*
w207	Lupin	*Lupinus* spp.
w210	Sugar-beet	*Beta vulgaris.*
w211	Par j 2.0101	*Parietaria judaica.*
w231	Art v 1	*Artemisia vulgaris* (Mugwort).
w232	Sal k 1	*Salsola kali.*
w233	Art v 3	*Artemisa vulgaris* (LTP, Mugwort).
w234	Pla l 1	*Plantago lanceolata.*
w235	Che a 1.0101	*Chenopodium album.*
w236	Mer a 1.0101	*Mercurialis annua.*
a753	Art v 1	*Artemisia vulgaris* (Mugwort weed).
	Tree Pollens	
t1	Box-elder (Maple)	*Acer negundo*, *Acer saccharum.*
t2	Gray alder, speckled alder (alder)	*Alnus incana.*
t4	Hazel, hazelnut	*Corylus avellana*, *Corylus americana.*
t5	American beech (beech)	*Fagus grandifolia* (*Fagus americana*).
t6	Mountain juniper, Mountain cedar	*Juniperus ashei* (*Juniperus sabinoides*).
t8	Elm	*Ulmus americana.*
t9	Olive	*Olea europaea.*
t10	Walnut	*Juglans californica*, *Juglans nigra.*
t11	Maple leaf sycamore, London plane, Plane tree	*Platanus acerifolia.*
t61	Sycamore	*Platanus occidentalis.*
t12	Willow	*Salix caprea*, *Salix nigra.*
t14	Cottonwood (Eastern Cottonwood/Black Cottonwood)	*Populus deltoides.*
t15	White ash	*Fraxinus americana.*
t16	White pine	*Pinus strobus.*
t18	Eucalyptus, gum-tree	*Eucalyptus globulus* (*Eucalyptus* spp.).
t19/t26	Acacia	*Acacia longifolia* (*Acacia* spp.).
t20	Mesquite	*Prosopis glandulosa/Prosopis juliflora.*
t21	Melaleuca, cajeput tree	*Melaleuca quinquenervia* (*Melaleuca leucadendron*).
t22	Pecan, hickory	*Carya illinoinensis* (*Carya pecan*).
t23	Italian/Mediterranean/funeral cypress	*Cupressus sempervirens.*
t24	Japanese cypress	*Chamaecyparis obtusa* (*Chamaecyparis* spp.).
t25	Ash	*Fraxinus excelsior.*
t27	Maple, red	*Acer rubrum.*
t29	Acacia	*Acacia* spp.
t30	Birch, white	*Betula populifolia.*
t32	Willow, black	*Salix nigra.*
t33	Ash, Arizona	*Fraxinus velutina.*
t35	Cedar, salt	*Tamarix gallica.*
t37	Bald cypress (white bald cypress)	*Taxodium distichum.*
t38	Elm, Chinese/Siberian	*Ulmus pumila.*
t40	Hazelnut tree	*Corylus americana.*
t41	White hickory	*Carya alba* (*Carya tomentosa*).
t42	Oak, red	*Quercus rubra.*
t43	Loblolly pine	*Pinus taeda.*
t44	Hackberry	*Celtis occidentalis.*
t45	Cedar elm	*Ulmus crassifolia.*
t47	Juniper, one seed	*Juniperus monosperma.*
t48	Pine, lodgepole	*Pinus contorta.*
t49	Pine, ponderosa	*Pinus ponderosa.*
t50	Beech, European	*Fagus sylvatica.*
t51	Tree of Heaven	*Ailanthus altissima.*
t52	Western white pine	*Pinus monticola.*
t54	Russian olive	*Elaeagnus angustifolia.*
t55	Scotch broom	*Cytisus scoparius.*
t56	Bayberry	*Myrica cerifera.*
t57	Red cedar	*Juniperus virginiana.*
t60	Western juniper	*Juniperus occidentalis.*
t61	Sycamore	*Platanus occidentalis.*
t70	Mulberry (white mulberry)	*Morus alba.*
t71	Red mulberry	*Morus rubra.*
t72	Queen palm	*Arecastrum romanzoffiamon.*
t73	Australian pine	*Casuarina equisetifolia.*

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

Allergen code	Allergen product	Source (taxonomical name)
t77	Oak mix (red, white, black)	*Quercus* spp.
t80	Japanese cypress	*Chamaecyparis obtusa.*
t81	Japanese alder	*Alnus japonica.*
t83	Mango tree	*Mangifera indica.*
t90	Walnut, black	*Juglans nigra.*
t96	Poplar, white (poplar)	*Populus alba.*
t103/t218	Virginia live oak (live oak)	*Quercus virginiana.*
t105	Pepper tree	*Schinus molle.*
t110	Orange tree	*Citrus sinensis.*
t201	Spruce, Norway spruce	*Picea abies* (*Picea excelsa*).
t202	Alder, smooth	*Alnus incana* spp. *Rugosa* (*Alnus rugosa*).
t203	Horse chestnut	*Aesculus hippocastanum.*
t205	Elder	*Sambucus nigra.*
t206	Chestnut	*Castanea sativa.*
t207	Douglas fir	*Pseudotsuga menziesii* (*Pseudotsuga taxifolia*).
t208	Linden	*Tilia cordata.*
t209	Horn beam	*Carpinus betulus.*
t210	Privet	*Ligustrum vulgare.*
t211	Sweet gum	*Liquidambar styraciflua.*
t212	Cedar	*Libocedrus decurrens.*
t213	Pine	*Pinus radiata.*
t214	Date palm	*Phoenix canariensis.*
t215	Lilac	*Syringa vulgaris.*
t217	Pepper tree	*Schinus molle.*
t217	Red alder	*Alnus rubra.*
t218	Virginia live oak	*Quercus virginiana.*
t218	Bayberry (bayberry/sweet gale)	*Myrica gale.*
t219	Palo verde	*Cercidium floridum.*
t219	Red cedar	*Juniperus virginiana.*
t220	Bet v 4	*Betula verrucosa* (Birch).
t221	Bet v 2.0101, Bet v 4	*Betula verrucosa* (Birch).
t222	Cypress (Arizona cypress)	*Cupressus arizonica.*
t223	Oil palm	*Elaeis guineensis.*
t224	Ole e 1	*Olea europaea.*
t225	Bet v 6	*Betula verrucosa* (Birch).
t226	Cup a 1	*Cupressus arizonica.*
t227	Ole e 7	*Olea Europaea.*
t228	Aspen, quaking	*Populus tremuloides.*
t229	Eastern hemlock	*Tsuga canadensis.*
t230	Redwood (sequoia)	*Sequoia sempervirens.*
t232	Pussy willow	*Salix discolor.*
t240	Ole e 9.0101	*Olea Europaea.*
t241	Pla a 1.0101	*Platanus acerifolia.*
t242	Pla a 2	*Platanus acerifolia.*
t243	Pla a 3.0101	*Platanus acerifolia.*
t244	Cor a 1.0103	*Corylus avellana.*
t245	Aln g 1.0101	*Alnus glutinosa.*
t246	Cry j 1	*Cryptomeria japonica.*
t280	Locust tree	*Robinia pseudoacacia.*
t401	Brazilian peppertree	*Schinus terebinthifolius.*
t402	Mastic tree	*Pistacia lentiscus.*
t404	Tree of heaven	*Ailanthus altissima.*
t406	Date palm	*Phoenix dactylifera.*
a482	Ole e 1	*Olea europaea* (Olive Oil).
	Mites	
d207	Blo t 5.0101	*Blomia tropicalis.*
d208	Lep d 2.0101	*Lepidoglyphus destructor.*
	Microorganisms, Molds, Yeast	
m1	*Penicillium chrysogenum* (*Penicillium notatum*)	*Penicillium chrysogenum* (*Penicillium notatum*).
m2	*Cladosporium herbarum* (*Hormodendrum*)	*Cladosporium herbarum* (*Hormodendrum*).
m3	*Aspergillus fumigatus*	*Aspergillus fumigatus.*
m4	*Mucor racemosus*	*Mucor racemosus.*
m5	*Candida albicans*	*Candida albicans.*
m7	*Botrytis cinerea*	*Botrytis cinerea.*
m8	*Drechslera halodes* (*Setomelanomma rostrata, Helminthosporium halodes, Helminthosporium interseminatum*).	*Drechslera halodes* (*Setomelanomma rostrata, Helminthosporium halodes.*

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

Allergen code	Allergen product	Source (taxonomical name)
m9	*Fusarium moniliforme* (*Fusarium proliferatum*)	*Fusarium moniliforme* (*Fusarium proliferatum*).
m10	*Stemphylium botryosum*	*Stemphylium herbarum* (*Stemphylium botryosum*).
m11	*Rhizopus nigricans*	*Rhizopus nigricans.*
m12	*Aureobasidium pullulans*	*Aureobasidium pullulans.*
m13	*Phoma betae*	*Phoma betae.*
m14	*Epicoccum purpurascens*	*Epicoccum purpurascens* (*Epicoccum nigrum*).
m15	*Trichoderma viride*	*Trichoderma viride.*
m16	*Curvularia lunata*	*Curvularia lunata*, *Curvularia specifera* (*K923044*).
m17	*Cladosporium fulvum*	*Cladosporium fulvum.*
m18	*Fusarium culmorum*	*Fusarium culmorum.*
m19	*Aspergillus versicolor*	*Aspergillus versicolor.*
m20	*Mucor mucedo*	*Mucor mucedo.*
m21	*Aspergillus clavatus*	*Aspergillus clavatus.*
m22	*Micropolyspora faeni*	*Saccharopolyspora rectivirgula* (*Micropolyspora faeni*).
m23	*Thermoactinomyces vulgaris*	*Thermoactinomyces vulgaris.*
m24	*Stachybotrys atra*	*Stachybotrys chartarum* (*Stachybotrys atra*).
m24	*Paecilomyces* spp	*Paecilomyces* spp.
m25	*Aspergillus versicolor*	*Aspergillus versicolor.*
m25	*Penicillium brevicompactum*	*Penicillium brevicompactum.*
m26	*Cladosporium cladosporioides*	*Cladosporium cladosporioides.*
m26	*Penicillium citrinum*	*Penicillium citrinum.*
m27	*Penicillium* spp	*Penicillium* spp.
m29	*Aspergillus repens*	*Aspergillus repens.*
m30	*Penicillium roqueforti*	*Penicillium roqueforti.*
m32	*Cladosporium cladosporioides*	*Cladosporium cladosporioides.*
m34	*Serpula lacrymans*	*Serpula lacrymans.*
m36	*Aspergillus terreus*	*Aspergillus terreus.*
m37	*Trichophyton mentagrophytes*	*Trichophyton mentagrophytes.*
m40	*Aspergillus amstelodami*	*Aspergillus amstelodami.*
m43	*Saccharomyces Carlsberg*	*Saccharomyces carlsbergensis.*
m44	*Saccharomyces cerevisiae*	*Saccharomyces cerevisiae.*
m45	*Hormodendrum hordei*	*Hormodendrum hordei.*
m46	*Bipolaris spicifera*	*Bipolaris spicifera.*
m47	*Aspergillus nidulans*	*Aspergillus nidulans.*
m48	*Aspergillus oryzae*	*Aspergillus oryzae.*
m49	*Fusarium oxysporum*	*Fusarium oxysporum.*
m50	*Micropolyspora faeni*	*Saccharopolyspora rectivirgula* (*Micropolyspora faeni*).
m51	*Thermoactinomyces vulgaris*	*Thermoactinomyces vulgaris.*
m53	*Microspora canis*	*Microsporum canis* (*Microspora canis*).
m54	*Aspergillus flavus*	*Aspergillus flavus.*
m63	*Helminthosporium intersemin*	*Helminthosporium intersemin.*
m66	*Mucor plumbeus*	*Mucor plumbeus.*
m67	*Mycogone*	*Mycogone perniciosa.*
m68	*Nigrospora oryzae*	*Nigrospora oryzae.*
m69	*Rhodotorula*	*Rhodotorula rubra* (*Rhodotorula mucilaginosa*).
m70	*Malassezia furfur* (*Pityrosporum orbiculare*)	*Malassezia furfur* (*Pityrosporum orbiculare*).
m71	*Spondylocladium*	*Spondylocladium* spp.
m72	*Epidermophyton*	*Epidermophyton floccosum.*
m73	*Epicoccum nigrum*	*Epicoccum purpurascens* (*Epicoccum nigrum*).
m80	*Staphylococcal enterotoxin A* (*Sta a SEA*)	*Staphylococcus aureus.*
m80	*Helminthosporium* spp	*Helminthosporium* spp.
m81	*Staphylococcal enterotoxin B* (*Sta a SEB*)	*Staphylococcus aureus.*
m88	*Stemphylium solani*	*Stemphylium solani.*
m93	*Gliocladium fimbriatum*	*Gliocladium fimbriatum.*
m94	*Phycomyces blakesleeanus*	*Phycomyces blakesleeanus.*
m201	*Tilletia tritici* (*Ustilago nuda, Ustilago tritici*) (Barley smut)	*Tilletia tritici* (*Ustilago nuda, Ustilago tritici*).
m202	*Acremonium kiliense* (*Cephalosporium acremonium*)	*Acremonium kiliense* (*Cephalosporium acremonium*).
m203	*Trichosporon pullulans*	*Trichosporon pullulans.*
m204	*Ulocladium chartarum*	*Ulocladium chartarum.*
m205	*Trichophyton rubrum*	*Trichophyton rubrum.*
m207	*Aspergillus niger*	*Aspergillus niger.*
m208	*Chaetomium globosum*	*Chaetomium globosum.*
m209	*Penicillium frequentans*	*Penicillium glabrum* (*Penicillium frequentans*).
m209	*Stachybotrys chartarum*	*Stachybotrys chartarum* (*Stachybotrys atra*).
m210	*Trichophyton mentagrophytes var. goetzii*	*Trichophyton mentagrophytes var. goetzii.*
m211	*Trichophyton mentagrophytes var. interdigitale*	*Trichophyton mentagrophytes var. interdigitale.*
m211	Oat smut	*Ustilago avenae.*
m212	*Micropolyspora faeni*	*Saccharopolyspora rectivirgula* (*Micropolyspora faeni*).
m212	*Geotrichum candidum*	*Geotrichum candidum.*
m213	Bermuda grass smut	*Ustilago cynodontis.*

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

Allergen code	Allergen product	Source (taxonomical name)
m214	Johnson grass smut	*Sphacelotheca cruenta.*
m215	Corn smut	*Ustilago maydis.*
m218	Asp f 1.0101	*Aspergillus fumigatus.*
a3050	Asp r 1	*Aspergillus restrictus.*
m219	Asp f 2	*Aspergillus fumigatus.*
m220	Asp f 3.0101	*Aspergillus fumigatus.*
m221	Asp f 4	*Aspergillus fumigatus.*
m222	Asp f 6.0101	*Aspergillus fumigatus.*
m223	*Staphylococcal enterotoxin C* (*Sta a SEC*)	*Staphylococcus aureus.*
m224	*Staphylococcal enterotoxin D* (*Sta a SED*)	*Staphylococcus aureus.*
m226	*Staphylococcal enterotoxin TSST* (*Sta a TSST*)	*Staphylococcus aureus.*
m227	*Malassezia* spp. (*Pityrosporum* spp.)	*Malassezia* spp. (*Pityrosporum* spp.).
m228	*Aspergillus flavus*..	
m229	Alt a 1.0101	*Alternaria alternata* (*Alternaria tenuis*).
m230	Alt a 6.0101	*Alternaria alternata* (*Alternaria tenuis*).
m231	Cla h 8.0101	*Cladosporium herbarum* (*Hormodendrum*).
m300	*Eurotium* spp	*Eurotium* spp.
m304	*Aspergillus oryzae*	*Aspergillus oryzae.*
m305	*Penicillium brevicompactum*	*Penicillium brevicompactum.*
m309	*Aspergillus terreus*	*Aspergillus terreus.*
m310	*Aspergillus nidulans*	*Aspergillus nidulans.*
m311	*Aspergillus flavus*	*Aspergillus flavus.*
m312	*Aspergillus clavatus*	*Aspergillus clavatus.*
	Epidermal & Animal	
e6	Guinea pig epithelium	*Cavia porcellus.*
e7	Pigeon droppings	*Columba palumbus*, *Columba livia.*
e25	Chicken serum	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
e26	Parrot serum	*Psittacoidea* spp.
e62	Camel	*Camelus dromedaries.*
e70	Goose feathers	*Anser anser.*
e71	Mouse epithelium	*Mus musculus* (*Mus* spp.).
e73	Rat epithelium	*Rattus norvegicus.*
e74	Rat urine proteins	*Rattus norvegicus*, *Rattus rattus.*
e75	Rat serum proteins	*Rattus norvegicus*, *Rattus rattus.*
e76	Mouse serum proteins	*Mus musculus* (*Mus* spp.).
e77	Budgerigar droppings	*Melopsittacus undulatus.*
e78	Budgerigar feathers	*Melopsittacus undulatus.*
e79	Budgerigar serum proteins	*Melopsittacus undulatus.*
e80	Goat epithelium	*Capra hircus.*
e81	Sheep epithelium	*Ovis aries* (*Ovis* spp.).
e82	Rabbit epithelium	*Oryctolagus cuniculus* (*Oryctolagus* spp.).
e83	Swine epithelium	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
e84	Hamster epithelium	*Cricetus cricetus, Mesocricetus auratus, and Phodopus sungorus.*
e85	Chicken feathers	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
e86	Duck feathers	*Anas platyrhynchos.*
e87	Rat epithelium, serum proteins, and urine proteins	*Rattus norvegicus Rattus rattus.*
e88	Mouse epithelium, serum proteins, and urine proteins (mouse).	*Mus musculus* (*Mus* spp.).
e89	Turkey feathers	*Meleagris gallopavo.*
e90	Budgerigar serum proteins, feathers, and droppings	*Melopsittacus undulatus.*
e91	Pigeon serum proteins, feathers, and droppings	*Streptopelia roseogrisea*, *Psittacidae* spp.
e92	Parrot serum proteins, feathers, and droppings	*Ara* spp.
e93	Pigeon serum proteins	*Streptopelia roseogrisea.*
e94	Fel d 1.0101	*Felis domesticus.*
a345	Fel d 1	*Felis domesticus.*
e98	Parrot droppings	*Psittacoidea* spp.
e101	Can f 1.0101	*Canis familiaris* (*Canis domesticus*).
a174	Can f 1	*Canis familiaris* (*Canis domesticus*).
e102	Can f 2.0101	*Canis familiaris* (*Canis domesticus*).
e196	Parakeet feathers	*Nymphicus hollandicus.*
e197	Parakeet droppings	*Nymphicus hollandicus.*
e198	Parakeet serum	*Nymphicus hollandicus.*
e199	Canary bird serum	*Serinus canarius.*
e200	Canary bird droppings	*Serinus canarius.*
e201	Canary bird feathers (Canary feathers)	*Serinus canarius.*
e202	Reindeer epithelium	*Rangifer tarandus.*
e203	Mink epithelium	*Mustela* spp.

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

Allergen code	Allergen product	Source (taxonomical name)
e204	Bos d 6	*Bos domesticus* (*Bos taurus; Bos* spp.).
e205	Horse, serum proteins	*Equus caballus* (*Equus* spp.).
e206	Rabbit, serum proteins	*Oryctolagus cuniculus* (*Oryctolagus* spp.).
e208	Chinchilla epithelium	*Chinchilla laniger.*
e209	Gerbil epithelium	*Meriones unguiculatus.*
e210	Fox epithelium	*Vulpes vulpes.*
e211	Rabbit, urine proteins	*Oryctolagus cuniculus* (*Oryctolagus* spp.).
e212	Swine, urine proteins	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
e213	Parrot feathers	*Ara* spp.
e214	Finch feathers	*Lonchura domestica.*
e215	Pigeon feathers	*Streptopelia roseogrisea* (*Streptopelia* spp.), *Columbia* spp.
e216	Deer epithelium	*Dama dama.*
e217	Ferret epithelium	*Mustela putorius.*
e218	Chicken droppings	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
e219	Chicken, serum proteins	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
e220	Fel d 2, Cat serum albumin	*Felis domesticus.*
e221	Can f 3	*Canis familiaris* (*Canis domesticus*) (*Dog serum albumin*).
e222	Swine serum albumin (Sus s PSA)	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
e225	Lovebird feathers	*Psittacoidea agapomis.*
e226	Can f 5.0101	*Canis familiaris.*
e227	Equ c 1.0101	*Equus caballus.*
e228	Fel d 4.0101	*Felis domesticus.*
e230	Equ c 3	*Equus caballus.*
e231	Mus m 1	*Mus musculus.*
	Food	
f9	Rice	*Oryza sativa.*
f12	Pea (green pea)	*Pisum sativum.*
f15	White bean	*Phaseolus vulgaris.*
f19	Cayenne pepper	*Capsicum frutescens* (*Capsicum annum*).
f21	Sugar cane	*Saccharum officinarum.*
f22	Raspberry	*Rubus idaeus.*
f26	Pork	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
f29	Watermelon	*Citrullus lanatus* (*Citrullus vulgaris*).
f31	Carrot	*Daucus carota.*
f32	Oyster mushroom	*Pleurotus ostreatus.*
f33	Orange	*Citrus sinensis.*
f35	Potato	*Solanum tuberosum.*
f43	Mother's milk	*Homo sapiens.*
f44	Strawberry	*Fragaria vesca* (*Fragaria* spp.).
f45	Yeast, baker's	*Saccharomyces cerevisiae.*
f46	Pepper, Red	*Capsicum annuum.*
f47	Garlic	*Allium sativum.*
f48	Onion	*Allium cepa.*
f49	Apple	*Malus x domestica* (*Malus* spp.).
f51	Bamboo shoot	*Phyllostachys pubescens.*
f52	Cacao/chocolate	*Theobroma cacao.*
f54	Sweet potato	*Ipomoea batatas.*
f55	Common millet	*Panicum miliaceum.*
f56	Foxtail millet	*Setaria italica.*
f57	Japanese millet	*Echinochloa crus-galli.*
f58	Pacific squid	*Todarodes pacificus.*
f59	Octopus	*Octopus vulgaris* (*Octopus* spp.).
f63	Kefir	NA.
f67	Parmesan cheese	NA.
f81	Cheese, cheddar type	NA.
f82	Cheese, mold type	NA.
f83	Chicken	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
f86	Parsley	*Petroselinum crispum.*
f87	Melon	*Cucumis melo Cucumis melo + Citrullus lanatus.*
f88	Mutton (lamb)	*Ovis aries* (*Ovis* spp.).
f90	Malt	*Hordeum vulgare.*
f92	Banana	*Musa* spp.
f93	Cacao	*Theobroma cacao.*
f94	Pear	*Pyrus communis* (*Pyrus* spp.).
f97	Yam	*Dioscorea* spp. *Dioscorea opposita.*
f97	Chamomile tea	*Matricaria chamomilla.*
f98	Gliadin	*Triticum aestivum* (*Triticum* spp.).
f102	Cantaloupe	*Cucumis melo var. cantalupensis.*

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

Allergen code	Allergen product	Source (taxonomical name)
f105	Chocolate	*Theobroma cacao.*
f109	Cottonseed	*Gossypium hirsutum.*
f110	Giant radish	*Raphanus sativus.*
f118	Zucchini	*Cucurbita pepo.*
f119	Radish	*Raphanus sativus.*
f120	Venison	*Capreolus capeolus.*
f121	Pinto bean	*Phaseolus vulgaris.*
f122	Cheese, American	NA.
f127	Black-eyed pea	*Vigna unguiculata.*
f131	Black Olive	*Olea europaea.*
f136	Red beet	*Beta vulgaris var. conditiva.*
f139	Goat's Cheese	*Capra aegagrus.*
f140	Bran	NA.
f141	Corn (vegetables)	*Zea mays.*
f152	Green bell pepper	*Capsicum annuum.*
f155	Brewer's yeast	*Saccharomyces carlsbergensis.*
f157	Duck	*Anas domesticus.*
f158	Goose	*Anser anser.*
f160	Camembert cheese	NA.
f162	Nectarine	*Prunus persica var. nucipersica.*
f163	Kohlrabi	*Brassica oleracea var. gongylodes.*
f65	Perch.	
f166	Leek	*Allium porrum.*
f170	Cheese (Switzerland) (Swiss cheese)	NA.
f174	Fig	*Ficus carica.*
f177	Cranberry	*Vaccinium macrocarpon.*
f179	Raisin	*Vitis* spp.
f182	Lima bean	*Phaseolus lunatus.*
f198	Flaxseed (bruised grain)	*Linum usitatissimum.*
f199	Untreated native milk	*Bos domesticus* (*Bos taurus; Bos* spp.).
f208	Lemon	*Citrus limon.*
f209	Grapefruit	*Citrus paradisi.*
f210	Pineapple	*Ananas comosus.*
f211	Blackberry	*Rubus fruticosus.*
f212	Mushroom (champignon)	*Agaricus hortensis* (*Agaricus* spp.).
f213	Rabbit	*Oryctolagus cuniculus* (*Oryctolagus* spp.).
f214	Spinach	*Spinacia oleracea.*
f215	Lettuce	*Lactuca sativa.*
f216	Cabbage	*Brassica oleracea var. capitata.*
f217	Brussels sprouts	*Brassica oleracea var. gem.*
f218	Paprika, sweet pepper	*Capsicum annuum.*
f219	Fennel seed	*Foeniculum vulgare.*
f219	Sage	*Salvia officinalis.*
f220	Cinnamon	*Cinnamomum* spp.
f221	Coffee	*Coffea* spp.
f222	Tea	*Camellia sinensis.*
f223	Green olive	*Olea europaea.*
f225	Summer squash, pumpkin	*Cucurbita pepo.*
f225	Pumpkin	*Cucurbita maxima.*
f226	Pumpkin seed	*Cucurbita pepo.*
f227	Sugar-beet seed	*Beta vulgaris.*
f229	Safflower Seed	*Carthamus tinctorius.*
f231	Milk, boiled	*Bos domesticus* (*Bos taurus; Bos* spp.).
f234	Vanilla	*Vanilla planifolia.*
f237	Apricot	*Prunus armeniaca.*
f241	Gouda cheese	NA.
f242	Cherry	*Prunus avium.*
f244	Cucumber	*Cucumis sativus.*
f246	Guar, guar gum	*Cyamopsis tetragonoloba.*
f247	Honey	NA.
f248	Rosemary	*Rosmarinus officinalis.*
f254	Plaice	*Pleuronectes platessa.*
f255	Plum	*Prunus domestica*, *Prunus americana.*
f258	Squid	*Loligo* spp.
f259	Grape	*Vitis vinifera* (*Vitis* spp.).
f260	Broccoli	*Brassica oleracea var. italica* (*Brassica oleracea var. cultivar*).
f261	Asparagus	*Asparagus officinalis.*
f262	Aubergine, eggplant	*Solanum melongena.*
f263	Green pepper	*Piper nigrum*, *Capsicum annuum.*

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

Allergen code	Allergen product	Source (taxonomical name)
f264	Eel	*Anguilla anguilla.*
f265	Caraway	*Carum carvi.*
f265	Cumin	*Cuminum cyminum.*
f266	Mace	*Myristica fragrans.*
f267	Cardamon	*Elettaria cardamomum.*
f268	Clove	*Syzygium aromaticum.*
f269	Basil	*Ocimum basilicum.*
f270	Ginger	*Zingiber officinale.*
f271	Anise	*Pimpinella anisum.*
f272	Tarragon	*Artemisia dracunculus.*
f273	Thyme	*Thymus vulgaris.*
f274	Marjoram	*Origanum majorana.*
f275	Lovage	*Levisticum officinale.*
f276	Fennel, fresh	*Foeniculum vulgare.*
f277	Dill	*Anethum graveolens.*
f278	Bay leaf	*Laurus nobilis.*
f279	Chili pepper	*Capsicum frutescens.*
f280	Black pepper	*Piper nigrum.*
f281	Curry (Santa Maria)	NA.
f282	Nutmeg	*Myristica fragrans.*
f283	Oregano	*Origanum vulgare.*
f284	Turkey meat	*Meleagris gallopavo.*
f285	Elk/moose meat	*Alces* spp.
f286	Mare's milk	*Equus caballus* (*Equus* spp.).
f287	Red kidney bean	*Phaseolus vulgaris.*
f288	Blueberry	*Vaccinium myrtillus* (*Vaccinium* spp.).
f289	Date	*Phoenix dactylifera.*
f291	Cauliflower	*Brassica oleracea var. botrytis.*
f292	Guava	*Psidium guajava.*
f293	Papaya	*Carica papaya.*
f294	Passion fruit, Maracuja	*Passiflora edulis* (*Passiflora* spp.).
f295	Carambola	*Averrhoa carambola.*
f296	Carob	*Ceratonia siliqua.*
f297	Gum Arabic	*Acacia senegal* (*Acacia* spp.).
f298	Tragacanth	*Astragalus* spp.
f299	Sweet chestnut (chestnut)	*Castanea sativa.*
f300	Pinto bean	*Phaseolus* spp.
f301	Persimmon (kaki fruit, sharon)	*Diospyros kaki.*
f302	Mandarin (tangerine, clementine, satsumas)	*Citrus reticulata.*
f305	Fenugreek	*Trigonella foenum-graecum.*
f306	Lime	*Citrus aurantifolia.*
f307	Hake	*Merluccius merluccius.*
f308	Sardine (pilchard)	*Sardina pilchardus.*
f310	Blue vetch	*Lathyrus sativus.*
f311	Megrim	*Lepidorhombus whiffiagonis.*
f315	Green bean	*Phaseolus vulgaris.*
f316	Rape seed	*Brassica napus.*
f317	Coriander	*Coriandrum sativum.*
f318	Jack fruit	*Artocarpus heterophyllus.*
f319	Beetroot	*Beta vulgaris.*
f320	Crayfish	*Astacus astacus.*
f321	Horse meat	*Equus caballus* (*Equus* spp.).
f322	Red currant	*Ribes sylvestre.*
f324	Hop (fruit cone)	*Humulus lupulus.*
f325	Saffron	*Colchicum autumnale.*
f328	Fig	*Ficus carica.*
f329	Watermelon	*Citrullus lanatus.*
f330	Rose hip	*Rosa* spp.
f331	Saffron	*Crocus sativus.*
f332	Mint	*Mentha piperita.*
f333	Linseed	*Linum usitatissimum.*
f336	Jujube	*Ziziphus jujuba.*
f336	Wine vinegar	*Vitis vinifera* (*Vitis* spp.).
f337	Sole	*Solea solea.*
f337	English sole	*Parophrys vetulus.*
f338	Wine, white	*Vitis vinifera* (*Vitis* spp.).
f339	Allspice	*Pimenta dioica.*
f339	Wine, red	*Vitis vinifera* (*Vitis* spp.).
f341	Cranberry	*Vaccinium oxycoccus*, *Vaccinium macrocarpon.*
f342	Olive (black, fresh)	*Olea europaea.*

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

Allergen code	Allergen product	Source (taxonomical name)
f343	Raspberry	*Rubus idaeus.*
f344	Sage	*Salvia officinalis.*
f346	Chives	*Allium schoenoprasum.*
f347	Quinoa	*Chenopodium quinoa.*
f348	Litchi	*Litchi chinensis.*
f349	Chum salmon roe	*Oncorhynchus keta.*
f358	Artichoke	*Cynara scolymus.*
f360	Yogurt	NA.
f368	Black bass	*Micropterus dolomieu* (*Micropterus dolomieui*).
f374	Karaya gum	*Sterculia urens.*
f375	Horseradish	*Armoracia rusticana.*
f377	Maple syrup	NA.
f379	Okra	*Abelmoschus esculentus.*
f382	Beet, sugar	*Beta vulgaris var. altissima.*
f401	Loquat	*Eriobotrya japonica.*
f402	Fig	*Ficus carica.*
f403	Brewer's yeast	*Saccharomyces cerevisiae.*
f405	Mint	*Mentha* spp.
f406	Arugula	*Eruca vesicaria.*
	House Dust	
h1	Greer Labs., Inc	NA.
h2	Hollister-Stier Labs	NA.
h6	Japan	NA.
	Venoms & Insects	
i7	Midge	*Chironomus yoshimatsui.*
i8	Moth	*Bombyx mori*, *Heterocera* spp.
i47	Water flea	*Daphnia* spp.
i49	Deer fly	*Chrysops* spp.
i51	Black ant	*Camponotus pennsylvanicus.*
i54	Flea mix (dog/cat), common flea	*Ctenocephalides* spp.
i71	Mosquito	*Aedes communis*, *Aedes* spp. *and Culex* spp.
i72	Green nimitti	*Cladotanytarsus lewisi.*
i73	Blood worm	*Chironomus thummi*, *Chironomusri parius*, *Chironomus* spp.
i75	European hornet	*Vespa crabro.*
i76	Berlin beetle	*Trogoderma angustum.*
i77	European paper wasp	*Polistes dominulus.*
i78	Fly	*Musca domestica.*
i80	Bumblebee	*Bombus pennsylvanicus.*
i201	Horse bot fly	*Gasterophilus intestinalis.*
i202	Grain weevil	*Sitophilus granarius.*
i203	Mediterranean flour moth	*Ephestia kuehniella* (*Anagasta kuehniella*).
i204	Horse fly	*Tabanus* spp.
i205	Bumblebee	*Bombus terrestris.*
i208	Api m 1.0101	*Apis mellifera.*
a45	Api m 1	*Apis mellifera.*
i209	Ves v 5.0101	*Vespula vulgaris.*
a670	Ves v 5	*Vespula vulgaris.*
i210	Pol d 5.0101	*Polistes dominulus.*
i211	Ves v 1.0101	*Vespula vulgaris.*
i213	Api m 4	*Apis mellifera.*
i214	Api m 2	*Apis mellifera.*
i215	Api m 3	*Apis mellifera.*
i216	Api m 5	*Apis mellifera.*
i217	Api m 10	*Apis mellifera.*
i220	Bla g 1.0101	*Blattella germanica.*
i221	Bla g 2.0101	*Blattella germanica.*
i222	Bla g 5.0101	*Blattella germanica.*
i223	Bla g 7	*Blattella germanica.*
a46	Api m 2	*Apis mellifera.*
	Miscellaneous	
o1	Cotton, crude fibers	*Gossypium* spp.
o3	Cotton (treated)	*Gossypium* spp.
o70	Seminal fluid	*Homo sapiens.*
o71	*Staphylococcus aureus*	*Staphylococcus aureus.*

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

Allergen code	Allergen product	Source (taxonomical name)
o72	*Pichia pastoris* crude extract customer specific	*Pichia pastoris.*
o72	Sperm-sediment	*Homo sapiens.*
o73	*Pichia pastoris* crude extr. vector customer specific	*Pichia pastoris.*
o74	*Pichia pastoris* with vector customer specific	*Pichia pastoris.*
o201	Tobacco leaf, tobacco dust	*Nicotiana tabacum.*
o202	Artemia salina, fish feed	*Artemia salina.*
o203	Tetramin, fish feed	NA.
o207	Daphnia, fish feed	*Daphnia* spp.
o211	Mealworm	*Tenebrio molitor.*
o212	Streptavidin	*Streptomyces avidini.*
o213	MBP (maltose binding protein)	*Escherichia coli.*
o214	CCD; MUXF3 from bromelain	*Ananas comosus.*
o72	Enterotoxin A (Sta a SEA)	*Staphylococcus aureus.*
o73	Enterotoxin B (Sta a SEB)	*Staphylococcus aureus.*
	Parasites	
p1	Ascaris	*Ascaris suum.*
p2	Echinococcus	*Echinococcus granulosus.*
p3	Schistosoma	*Schistosoma mansoni.*
p4	Anisakis (Herring Worm)	*Anisakis simplex* (*Anisakis* spp.).
p5	Toxocara canis	*Toxocara canis.*
p10	Ani s 3.0101	*Anisakis simplex* (*Anisakis* spp.).
p11	Ani s 1	*Anisakis simplex* (*Anisakis* spp.).
	Occupational	
k4	Threshing dust	NA.
k5	Flax	NA.
k7	Hay Dust	NA.
k8	Hop (hops)	*Humulus lupulus.*
k12	Grain mill dust	NA.
k14	Kapok	NA.
k20	Sheep's wool (treated) (wool)	*Ovis aries* (*Ovis* spp.).
k21	Sheep's wool (Untreated)	*Ovis aries* (*Ovis* spp.).
k23	Straw Dust	NA.
k33	Oak	NA.
k70	Green coffee bean	*Coffea* spp.
k71	Castor bean	*Ricinus communis.*
k72	Ispaghula	*Plantago psyllium/Plantago ovata.*
k73	Silk waste	NA.
k74	Silk	*Bombyx mori.*
k75	Isocyanate TDI (Toluene diisocyanate)	NA.
k76	Isocyanate MDI (Diphenylmethane diisocyanate)	NA.
k77	Isocyanate HDI (Hexamethylen diisocyanate)	NA.
k78	Ethylene oxide	NA.
k79	Phthalic anhydride	NA.
k80	Formaldehyde/Formalin	NA.
k81	Ficus	*Ficus benjamina* (*Ficus* spp.).
k83	Cotton seed	*Gossypium hirsutum.*
k84	Sunflower seed	*Helianthus annuus.*
k85	Chloramin T	NA.
k86	Trimellitic anhydride, TMA	NA.
k87	Asp o 21, alpha-amylase	*Aspergillus oryzae.*
k89	Orris root	*Iris florentina.*
k99	HSA (Human Serum Albumin) (Hom s HSA)	*Homo sapiens.*
k201	Car p 1, Papain	*Carica papaya.*
k202	Ana c 2, Bromelain	*Ananas comosus.*
k204	Maxatase	*Bacillus licheniformis.*
k205	Alcalase	*Bacillus* spp.
k206	Savinase, Protease 1 (Bac l Subtilisin)	*Bacillus* spp.
k208	Gal d 4, Lysozyme	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
k209	Hexahydrophtalic anhydrid	NA.
k210	Maleic anhydride	NA.
k211	Methyltetrahydrophtalic anhydrid	NA.
k212	Abachi wood dust	*Triplochiton scleroxylon.*
k213	Pepsin (Sus s Pepsin)	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
k213	TCPA	NA.
k214	Bougainvillea	*Bougainvillea* spp.
k225	Horse radish peroxidase (Arm r HRP)	*Armoracia rusticana.*

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

Allergen code	Allergen product	Source (taxonomical name)
k226	Ascorbate oxidase (Cuc p ascorbate oxidase)	*Cucurbita pepo.*
k301	Flour dust	*Triticum* spp.
k501	Savinase customer specific	Proprietary knowledge of customer.
k502	Lipolase customer specific	Proprietary knowledge of customer.
k503	Termamyl customer specific	Proprietary knowledge of customer.
k504	Clazinase customer specific	Proprietary knowledge of customer.

■ 66. In § 866.5910, revise paragraph (b) to read as follows:

§ 866.5910 Quality control material for cystic fibrosis nucleic acid assays.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays.'' See § 866.1(e) for the availability of this guidance document.

PART 868—ANESTHESIOLOGY DEVICES

■ 67. The authority citation for part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 68. In § 868.1040, revise paragraph (b) to read as follows:

§ 868.1040 Powered algesimeter.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

■ 69. In § 868.2385, revise paragraph (b) to read as follows:

§ 868.2385 Nitrogen dioxide analyzer.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a standalone nitrogen dioxide analyzer and not those that are components of nitric oxide delivery systems intended to monitor nitrogen dioxide levels during inhaled nitric oxide therapy, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The special control is FDA's ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.'' See § 868.1(e) for the availability of this guidance document.

■ 70. In § 868.2500, revise paragraph (b) to read as follows:

§ 868.2500 Cutaneous oxygen (PcO2) monitor.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The special control is FDA's ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO2) and Oxygen (PcO2) Monitors; Guidance for Industry and FDA.'' See § 868.1(e) for the availability of this guidance document.

■ 71. In § 868.2550, revise paragraph (b) to read as follows:

§ 868.2550 Pneumotachometer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

■ 72. In § 868.5180, revise paragraph (b) to read as follows:

§ 868.5180 Rocking bed.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

■ 73. In § 868.6250, revise paragraph (b) to read as follows:

§ 868.6250 Portable air compressor.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

PART 870—CARDIOVASCULAR DEVICES

■ 74. The authority citation for part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 75. In § 870.1330, revise paragraph (b) to read as follows:

§ 870.1330 Catheter guide wire.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a torque device that is manually operated, non-patient contacting, and intended to manipulate non-cerebral vascular guide wires, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 76. In § 870.1390, revise paragraph (b) to read as follows:

§ 870.1390 Trocar.

* * * * *

(b) *Classification.* Class II (special controls). Except for trocars that are reprocessed for multiple use, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 77. In § 870.1650, revise paragraph (b) to read as follows:

§ 870.1650 Angiographic injector and syringe.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a non-patient contacting balloon inflation syringe intended only to inflate/deflate balloon catheters and monitor pressure within the balloon, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 78. In § 870.1875, revise paragraph (b)(2) to read as follows:

§ 870.1875 Stethoscope.

* * * * *

(b) * * *

(2) *Classification.* Class II (special controls). The device, when it is a lung sound monitor, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 79. In § 870.2675, revise paragraph (b) to read as follows:

§ 870.2675 Oscillometer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 80. In § 870.2770, revise paragraph (b) to read as follows:

§ 870.2770 Impedance plethysmograph.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a body composition analyzer which is not intended to diagnose or treat any medical condition, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 81. In § 870.4280, revise paragraph (b) to read as follows:

§ 870.4280 Cardiopulmonary prebypass filter.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 82. In § 870.4290, revise paragraph (b) to read as follows:

§ 870.4290 Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 83. In § 870.4340, revise paragraph (b) to read as follows:

§ 870.4340 Cardiopulmonary bypass level sensing monitor and/or control.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 84. In § 870.4400, revise paragraph (b) to read as follows:

§ 870.4400 Cardiopulmonary bypass blood reservoir.

* * * * *

(b) *Classification.* Class II (special controls), except that a reservoir that contains a defoamer or filter is classified into the same class as the defoamer or filter. The device, when it is a cardiopulmonary bypass blood reservoir that does not contain defoamers or blood filters, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 85. In § 870.4420, revise paragraph (b) to read as follows:

§ 870.4420 Cardiopulmonary bypass cardiotomy return sucker.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 86. In § 870.4430, revise paragraph (b) to read as follows:

§ 870.4430 Cardiopulmonary bypass intracardiac suction control.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

PART 872—DENTAL DEVICES

■ 87. The authority citation for part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 88. In § 872.1720, revise paragraph (b) to read as follows:

§ 872.1720 Pulp tester.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 89. In § 872.3260, revise paragraph (b) to read as follows:

§ 872.3260 Cavity varnish.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an external cleaning solution, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 90. In § 872.3300, revise paragraph (b) to read as follows:

§ 872.3300 Hydrophilic resin coating for dentures.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 91. In § 872.3540, revise paragraph (b)(2) introductory text to read as follows:

§ 872.3540 OTC denture cushion or pad.

* * * * *

(b) * * *

(2) Class II (special controls) if the OTC denture cushion or pad is made of a material other than wax-impregnated cotton cloth or if the intended use of the device differs from that described in paragraph (b)(1) of this section. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. The special controls for this device are FDA's:

* * * * *

■ 92. In § 872.3560, revise paragraph (b) introductory text to read as follows:

§ 872.3560 OTC denture reliner.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. The special controls for this device are FDA's:

* * * * *

■ 93. In § 872.3590, revise paragraph (b) to read as follows:

§ 872.3590 Preformed plastic denture tooth.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 94. In § 872.3600, revise paragraph (b) introductory text to read as follows:

§ 872.3600 Partially fabricated denture kit.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. The special controls for this device are FDA's:

* * * * *

■ 95. In § 872.3890, revise paragraph (b) to read as follows:

§ 872.3890 Endodontic stabilizing splint.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 96. In § 872.5550, revise paragraph (b)(2) to read as follows:

§ 872.5550 Teething ring.

* * * * *

(b) * * *

(2) Class II (special controls) if the teething ring contains a fluid, such as water. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 97. In § 872.6770, revise paragraph (b) to read as follows:

§ 872.6770 Cartridge syringe.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 98. The authority citation for part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 99. In § 874.1090, revise paragraph (b) to read as follows:

§ 874.1090 Auditory impedance tester.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a tympanometer or auditory impedance tester that complies with FDA-recognized consensus standard ANSI S3.39, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 100. In § 874.1120, revise paragraph (b) to read as follows:

§ 874.1120 Electronic noise generator for audiometric testing.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 101. In § 874.1325, revise paragraph (b) to read as follows:

§ 874.1325 Electroglottograph.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 102. In § 874.3310, revise paragraph (b) to read as follows:

§ 874.3310 Hearing aid calibrator and analysis system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 103. In § 874.3320, revise paragraph (b) to read as follows:

§ 874.3320 Group hearing aid or group auditory trainer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 104. In § 874.3330, revise paragraph (b) to read as follows:

§ 874.3330 Master hearing aid.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 105. In § 874.3430, revise paragraph (b) to read as follows:

§ 874.3430 Middle ear mold.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 106. In § 874.3730, revise paragraph (b) to read as follows:

§ 874.3730 Laryngeal prosthesis (Taub design).

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a voice amplification device, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

PART 876—GASTROENTEROLOGY–UROLOGY DEVICES

■ 107. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 108. In § 876.1500, revise paragraph (b)(1) to read as follows:

§ 876.1500 Endoscope and accessories.

* * * * *

(b) * * *

(1) Class II (special controls). The device, when it is an endoscope disinfectant basin, which consists solely of a container that holds disinfectant and endoscopes and accessories; an endoscopic magnetic retriever intended for single use; sterile scissors for cystoscope intended for single use; a disposable, non-powered endoscopic grasping/cutting instrument intended for single use; a diagnostic incandescent light source; a fiberoptic photographic light source; a routine fiberoptic light source; an endoscopic sponge carrier; a xenon arc endoscope light source; an endoscope transformer; an LED light source; or a gastroenterology-urology endoscopic guidewire, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

* * * * *

■ 109. In § 876.4020, revise paragraph (b) to read as follows:

§ 876.4020 Fiberoptic light ureteral catheter.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 110. In § 876.4270, revise paragraph (b) to read as follows:

§ 876.4270 Colostomy rod.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 111. In § 876.4400, revise paragraph (b) to read as follows:

§ 876.4400 Hemorrhoidal ligator.

* * * * *

(b) *Classification.* Class II (special controls). Except for a hemostatic metal clip intended for use in the gastrointestinal tract, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 112. In § 876.4500, revise paragraph (b) to read as follows:

§ 876.4500 Mechanical lithotriptor.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a biliary mechanical lithotripter, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 113. In § 876.4770, revise paragraph (b) to read as follows:

§ 876.4770 Urethrotome.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 114. In § 876.5010, revise paragraph (b) to read as follows:

§ 876.5010 Biliary catheter and accessories.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a bile collecting bag or a surgical biliary catheter that does not include a balloon component, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 115. In § 876.5025, revise paragraph (b) introductory text to read as follows:

§ 876.5025 Vibrator for climax control of premature ejaculation.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. The special controls for this device are:

* * * * *

■ 116. In § 876.5160, revise the section heading and paragraph (b) to read as follows:

§ 876.5160 Urological clamp.

* * * * *

(b) *Classification.* Class I (general controls). Except when intended for internal use, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 117. In § 876.5365, revise paragraph (b) to read as follows:

§ 876.5365 Esophageal dilator.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 118. In § 876.5520, revise paragraph (b)(1) to read as follows:

§ 876.5520 Urethral dilator.

* * * * *

(b) * * *

(1) Class II (special controls). Except when it is a mechanical urethral dilator, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

* * * * *

■ 119. In § 876.5630, revise paragraph (b) to read as follows:

§ 876.5630 Peritoneal dialysis system and accessories.

* * * * *

(b) *Classification.* Class II (special controls). The following accessories are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9: A catheter finger grip that is non-patient contacting and intended for single use with a peritoneal catheter; a continuous ambulatory peritoneal dialysis (CAPD) belt; and a catheter stand that does not include weigh scales.

■ 120. In § 876.5665, revise paragraph (b) to read as follows:

§ 876.5665 Water purification system for hemodialysis.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a water purification subsystem disinfectant, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 121. In § 876.5895, revise paragraph (b) to read as follows:

§ 876.5895 Ostomy irrigator.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 122. In § 876.5980, revise paragraph (b)(1) to read as follows:

§ 876.5980 Gastrointestinal tube and accessories.

* * * * *

(b) * * *

(1) Class II (special controls). The barium enema retention catheter and tip with or without a bag that is a gastrointestinal tube and accessory or a gastronomy tube holder accessory is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

* * * * *

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 123. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 124. In § 878.4370, revise paragraph (b) to read as follows:

§ 878.4370 Surgical drape and drape accessories.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an ear, nose, and throat surgical drape, a latex sheet drape with self-retaining finger cot, a disposable urological drape, a Kelly pad, an ophthalmic patient drape, an ophthalmic microscope drape, an internal drape retention ring (wound protector), or a surgical drape that does not include an antimicrobial agent, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

■ 125. In § 878.4495, revise paragraph (b) to read as follows:

§ 878.4495 Stainless steel suture.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a steel monofilament suture that is uncoated and does not incorporate barbs, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9. The special control for this device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

■ 126. In § 878.4580, revise paragraph (b) to read as follows:

§ 878.4580 Surgical lamp.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an operating room lamp, a surgical instrument light, a surgical floor standing light, an endoscopic surgical light, a surgical light connector, a ceiling mounted surgical light, a surgical light carrier, surgical light accessories, a surgical lamp, a remote illuminator, or an incandescent surgical lamp, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

■ 127. In § 878.5070, revise paragraph (b) to read as follows:

§ 878.5070 Air-handling apparatus for a surgical operating room.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an air handling bench apparatus, an air handling room apparatus, or an air handling enclosure apparatus, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 128. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 129. In § 880.5580, revise paragraph (b) introductory text to read as follows:

§ 880.5580 Acupuncture needle.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an acupuncture point locator or a single use acupuncture needle, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9. Acupuncture needles must comply with the following special controls:

* * * * *

■ 130. In § 880.5680, revise paragraph (b) to read as follows:

§ 880.5680 Pediatric position holder.

* * * * *

(b) *Classification.* Class I (general controls). Except when the device is an infant positioner for prescription use in highly monitored settings or an infant sleep position holder, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9. The device is exempt from the good manufacturing practice regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

■ 131. In § 880.5780, revise paragraph (a)(2) to read as follows:

§ 880.5780 Medical support stocking.

(a) * * *

(2) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

* * * * *

■ 132. In § 880.6250, revise paragraph (b) to read as follows:

§ 880.6250 Non-powdered patient examination glove.

* * * * *

(b) *Classification.* Class I (general controls). The device, when it is a finger cot, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

■ 133. In § 880.6375, revise paragraph (b) to read as follows:

§ 880.6375 Patient lubricant.

* * * * *

(b) *Classification.* Class I (general controls). Except when the device is a vaginal patient lubricant or an oral lubricant, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

■ 134. In § 880.6760, revise paragraph (b) to read as follows:

§ 880.6760 Protective restraint.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

PART 882—NEUROLOGICAL DEVICES

■ 135. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 136. In § 882.1020, revise paragraph (b) to read as follows:

§ 882.1020 Rigidity analyzer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

■ 137. In § 882.1030, revise paragraph (b) to read as follows:

§ 882.1030 Ataxiagraph.

* * * * *

(b) *Classification.* Class I (general controls). Except when the device is intended to provide an interpretation or a clinical implication of the measurement, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

■ 138. In § 882.1470, revise paragraph (b) introductory text to read as follows:

§ 882.1470 Computerized cognitive assessment aid.

* * * * *

(b) *Classification.* Class II (special controls). Except when the computerized cognitive assessment aid is intended for diagnostic assessment of specific diseases or conditions and relies on inputs from visual cues, auditory cues, and/or functional use of the hand, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The special control(s) for this device are:

* * * * *

■ 139. In § 882.1540, revise paragraph (b) to read as follows:

§ 882.1540 Galvanic skin response measurement device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

■ 140. In § 882.1560, revise paragraph (b) to read as follows:

§ 882.1560 Skin potential measurement device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

■ 141. In § 882.1855, revise paragraph (b) to read as follows:

§ 882.1855 Electroencephalogram (EEG) telemetry system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

■ 142. In § 882.4060, revise paragraph (b) to read as follows:

§ 882.4060 Ventricular cannula.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

■ 143. In § 882.4545, revise paragraph (b) to read as follows:

§ 882.4545 Shunt system implantation instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

■ 144. In § 882.5895, revise paragraph (b) introductory text to read as follows:

§ 882.5895 Vibratory counter-stimulation device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The special controls for this device are:

* * * * *

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 145. The authority citation for part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 146. In § 884.1630, revise paragraph (b) to read as follows:

§ 884.1630 Colposcope.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a standard colposcope (or colpomicroscope) that uses only a white light source, does not use filters other than a green filter, does not include image analysis software, and is not smartphone-based, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 147. In § 884.2990, revise paragraph (b) to read as follows:

§ 884.2990 Breast lesion documentation system.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a breast examination recording sheet, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9. The special control is FDA's guidance entitled ''Class II Special Controls Guidance Document: Breast Lesion Documentation System.'' See § 884.1(e) for the availability of this guidance document.

■ 148. In § 884.3200, revise paragraph (b) to read as follows:

§ 884.3200 Cervical drain.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 149. In § 884.4400, revise paragraph (b) to read as follows:

§ 884.4400 Obstetric forceps.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 150. In § 884.4530, revise paragraph (b)(1) to read as follows:

§ 884.4530 Obstetric-gynecologic specialized manual instrument.

* * * * *

(b) * * *

(1) Class II (special controls). The device, when it is an umbilical clamp with or without a cutter, a uterine tenaculum which is sterile and does not use suction and is intended for single use, a nonmetal vaginal speculum, or a fiberoptic nonmetal vaginal speculum, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

* * * * *

■ 151. In § 884.4900, revise paragraph (b) to read as follows:

§ 884.4900 Obstetric table and accessories.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 152. In § 884.5200, revise paragraph (b) introductory text to read as follows:

§ 884.5200 Hemorrhoid prevention pressure wedge.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9. The special controls for this device are:

* * * * *

■ 153. In § 884.5390, revise paragraph (b) to read as follows:

§ 884.5390 Perineal heater.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 154. In § 884.5400, revise paragraph (b) to read as follows:

§ 884.5400 Menstrual cup.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 155. In § 884.5425, revise paragraph (b)(2) to read as follows:

§ 884.5425 Scented or scented deodorized menstrual pad.

* * * * *

(b) * * *

(2) Class II (special controls) for scented or scented deodorized menstrual pads made of materials not described in paragraph (b)(1). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 156. In § 884.5435, revise paragraph (b) to read as follows:

§ 884.5435 Unscented menstrual pad.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9 only when the device is made of common cellulosic and synthetic material with an established safety profile.

■ 157. In § 884.6120, revise paragraph (b) to read as follows:

§ 884.6120 Assisted reproduction accessories.

* * * * *

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing). The device, when it is a simple embryo incubator with only temperature, gas, and humidity control; a syringe pump; a collection tube warmer; a dish/plate/microscope stage warmer; or a controlled-rate cryopreservation freezer, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 158. In § 884.6130, revise paragraph (b) to read as follows:

§ 884.6130 Assisted reproduction microtools.

* * * * *

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing). The device, when the assisted reproduction microtools (pipettes) are manufactured from glass, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 159. In § 884.6150, revise paragraph (b) to read as follows:

§ 884.6150 Assisted reproduction micromanipulators and microinjectors.

* * * * *

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 160. In § 884.6160, revise paragraph (b) to read as follows:

§ 884.6160 Assisted reproduction labware.

* * * * *

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing). The device, when

it is a dish or plate intended for general assisted reproduction technology procedures, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

PART 886—OPHTHALMIC DEVICES

■ 161. The authority citation for part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 162. In § 886.1120, revise paragraph (b) to read as follows:

§ 886.1120 Ophthalmic camera.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a photorefractor or a general-use ophthalmic camera, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 163. In § 886.1250, revise paragraph (b) to read as follows:

§ 886.1250 Euthyscope.

* * * * *

(b) *Classification.* (1) Class I (general controls) for the battery-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

(2) Class II (special controls) for the AC-powered device. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 164. In § 886.1570, revise paragraph (b) to read as follows:

§ 886.1570 Ophthalmoscope.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an AC-powered opthalmoscope, a battery-powered opthalmoscope, or a hand-held ophthalmoscope replacement battery, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 165. In § 886.1780, revise paragraph (b)(1) to read as follows:

§ 886.1780 Retinoscope.

* * * * *

(b) * * *

(1) Class II (special controls) for the AC-powered device. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

* * * * *

■ 166. In § 886.1850, revise paragraph (b) to read as follows:

§ 886.1850 AC-powered slitlamp biomicroscope.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is intended only for the visual examination of the anterior segment of the eye, is classified as Group 1 per FDA-recognized consensus standard ANSI Z80.36, does not provide any quantitative output, and is not intended for screening or automated diagnostic indications, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 167. In § 886.1945, revise paragraph (b) to read as follows:

§ 886.1945 Transilluminator.

* * * * *

(b) *Classification.* (1) Class I (general controls) for the battery-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

(2) Class II (special controls) for the AC-powered device. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 168. In § 886.3320, revise paragraph (b) to read as follows:

§ 886.3320 Eye sphere implant.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an ocular peg which is supplied sterile only, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 169. In § 886.4070, revise paragraph (b) to read as follows:

§ 886.4070 Powered corneal burr.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 170. In § 886.4150, revise paragraph (b) to read as follows:

§ 886.4150 Vitreous aspiration and cutting instrument.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is phacofragmentation unit replacement tubing, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 171. In § 886.4250, revise paragraph (b) to read as follows:

§ 886.4250 Ophthalmic electrolysis unit.

* * * * *

(b) *Classification.* (1) Class I (general controls) for the battery-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

(2) Class II (special controls) for the AC-powered device. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 172. In § 886.4335, revise paragraph (b) to read as follows:

§ 886.4335 Operating headlamp.

* * * * *

(b) *Classification.* (1) Class I (general controls) for the battery-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

(2) Class II (special controls) for the AC-powered device. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 173. In § 886.4400, revise paragraph (b) to read as follows:

§ 886.4400 Electronic metal locator.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 174. In § 886.4440, revise paragraph (b) to read as follows:

§ 886.4440 AC-powered magnet.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 175. In § 886.4790, revise paragraph (b) to read as follows:

§ 886.4790 Ophthalmic sponge.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

PART 888—ORTHOPEDIC DEVICES

■ 176. The authority citation for part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 177. In § 888.1240, revise paragraph (b) to read as follows:

§ 888.1240 AC-powered dynamometer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 888.9.

■ 178. In § 888.4580, revise paragraph (b) to read as follows:

§ 888.4580 Sonic surgical instrument and accessories/attachments.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 888.9.

PART 890—PHYSICAL MEDICINE DEVICES

■ 179. The authority citation for part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 180. In § 890.1450, revise paragraph (b) to read as follows:

§ 890.1450 Powered reflex hammer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 181. In § 890.5100, revise paragraph (b) to read as follows:

§ 890.5100 Immersion hydrobath.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a hydromassage bath or a powered sitz bath, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 182. In § 890.5110, revise paragraph (b) to read as follows:

§ 890.5110 Paraffin bath.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 183. In § 890.5250, revise paragraph (b) to read as follows:

§ 890.5250 Moist steam cabinet.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 184. In § 890.5360, revise paragraph (b) to read as follows:

§ 890.5360 Measuring exercise equipment.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a measuring exerciser, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 185. In § 890.5500, revise paragraph (b) to read as follows:

§ 890.5500 Infrared lamp.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an infrared therapeutic heating lamp, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 186. In § 890.5575, revise paragraph (b) to read as follows:

§ 890.5575 Powered external limb overload warning device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

PART 892—RADIOLOGY DEVICES

■ 187. The authority citation for part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 188. In § 892.1000, revise paragraph (b) to read as follows:

§ 892.1000 Magnetic resonance diagnostic device.

* * * * *

(b) *Classification.* Class II (special controls). A magnetic resonance imaging disposable kit intended for use with a magnetic resonance diagnostic device only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 189. In § 892.1560, revise paragraph (b) to read as follows:

§ 892.1560 Ultrasonic pulsed echo imaging system.

* * * * *

(b) *Classification.* Class II (special controls). A biopsy needle guide kit intended for use with an ultrasonic pulsed echo imaging system only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 190. In § 892.1610, revise paragraph (b) to read as follows:

§ 892.1610 Diagnostic x-ray beam-limiting device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 191. In § 892.1650, revise paragraph (b) to read as follows:

§ 892.1650 Image-intensified fluoroscopic x-ray system.

* * * * *

(b) *Classification.* Class II (special controls). An anthrogram tray or radiology dental tray intended for use with an image-intensified fluoroscopic x-ray system only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9. In addition, when intended as an accessory to the device described in paragraph (a) of this section, the fluoroscopic compression device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 192. In § 892.1670, revise paragraph (b) to read as follows:

§ 892.1670 Spot-film device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 193. In § 892.1680, revise paragraph (b) to read as follows:

§ 892.1680 Stationary x-ray system.

* * * * *

(b) *Classification.* Class II (special controls). A radiographic contrast tray or radiology diagnostic kit intended for use with a stationary x-ray system only is exempt from the premarket notification procedures in subpart E of

part 807 of this chapter subject to the limitations in § 892.9.

■ 194. In § 892.1730, revise paragraph (b) to read as follows:

§ 892.1730 Photofluorographic x-ray system.

* * * * *

(b) *Classification.* Class II (special controls). A discography kit intended for use with a photofluorographic x-ray system only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 195. In § 892.1820, revise paragraph (b) to read as follows:

§ 892.1820 Pneumoencephalographic chair.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 196. In § 892.1850, revise paragraph (b) to read as follows:

§ 892.1850 Radiographic film cassette.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 197. In § 892.1860, revise paragraph (b) to read as follows:

§ 892.1860 Radiographic film/cassette changer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 198. In § 892.1870, revise paragraph (b) to read as follows:

§ 892.1870 Radiographic film/cassette changer programmer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 199. In § 892.1900, revise paragraph (b) to read as follows:

§ 892.1900 Automatic radiographic film processor.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 200. In § 892.2030, revise paragraph (b) to read as follows:

§ 892.2030 Medical image digitizer.

* * * * *

(b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std.). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 201. In § 892.2040, revise paragraph (b) to read as follows:

§ 892.2040 Medical image hardcopy device.

* * * * *

(b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 202. In § 892.5730, revise paragraph (b) to read as follows:

§ 892.5730 Radionuclide brachytherapy source.

* * * * *

(b) *Classification.* Class II (special controls). A prostate seeding kit intended for use with a radionuclide brachytherapy source only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

Dated: December 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27394 Filed 12–27–19; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 225

[Docket ID: DOD–2019–OS–0131]

RIN 0790–AK92

Commissary Credit and Debit Card User Fee

AGENCY: Department of Defense (DoD).

ACTION: Interim final rule.

SUMMARY: This rule implements Section 621 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 expanding patronage for commissary, exchange, and revenue-generating morale, welfare, and recreation (MWR) facilities. As part of DOD's implementation the Department is required to collect a user fee when these new populations utilize a credit or debit card that creates a cost to the Department of the Treasury for processing these transactions. As it related to this Section, such costs are only generated by credit or debit card transactions at Defense Commissary Agency (DeCA) facilities.

DATES: *Effective date:* This interim final rule is effective on December 30, 2019.

Comment date: Comments will be received by February 28, 2020.

Applicability date: Per the deadline in the statute and as implemented in this rule, these user fees go into effect on January 1, 2020.

ADDRESSES: You may submit comments, identified by docket number and or Regulatory Information Number (RIN) and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number or RIN. The general policy for comments and other submissions from members of the public is to make these submissions available at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Jane Westbay, (571) 372–6579, *Jane.A.Westbay.civ@mail.mil*.

SUPPLEMENTARY INFORMATION:

Summary of New and Amendatory Regulatory Provisions and Their Impact

This rule implements Section 621 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Purple Heart and Disabled Veterans Equal Access Act of 2018), codified at Section 1065 of Title 10, United States Code. Section 621 expands patronage for commissary, exchange, and revenue-generating morale, welfare, and recreation (MWR) facilities. By January 1, 2020, the Department of Defense is directed to: