Proposed Rules

Federal Register
Vol. 71, No. 185
Monday, September 25, 2006

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, and 892

[Docket No. 2006N–0335]

Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend certain classification regulations to reflect the termination of certain device exemptions and the requirement to submit validation data for specific reprocessed single-use devices (SUDs), as required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This proposed rule is a companion document to a direct final rule published elsewhere in this issue of the **Federal Register**. This proposed rule will provide a procedural framework to finalize the rule in the event we receive any significant adverse comment and withdraw the direct final rule. This proposed rule would codify actions taken in previous **Federal Register** notices in accordance with MDUFMA.

DATES: Submit written or electronic comments by December 11, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2006N–0335, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190, ext. 143.

SUPPLEMENTARY INFORMATION:

I. Why Is This Rule Being Issued as a Companion Proposed Rule?

This proposed rule is a companion to the direct final rule that is published in the final rules section of this issue of the **Federal Register**. The direct final rule would amend certain classification regulations for reprocessed single-use devices (SUDs) whose exemption from premarket notification (510(k)) requirements have been terminated and other reprocessed SUDs already subject to premarket notification for which validation data, as specified under MDUFMA, are necessary in a 510(k). The direct final rule and this companion proposed rule are identical. We are publishing the direct final rule because we believe the rule contains noncontroversial changes and minor corrections to existing regulations, and we anticipate that it will receive no significant adverse comment. A detailed discussion of the rule is set forth in the preamble of the direct final rule. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a confirmation document within 30 days after the comment period ends confirming when the direct final rule will go into effect. You can find additional information about FDA's direct final rulemaking procedures in the guidance document entitled ''Guidance for FDA and Industry: Direct Final Rule Procedures'' (62 FR 62466, November 21, 1977). This guidance document may be accessed at *http://www.fda.gov/opacom/morechoices/industry/guidance.htm*.

If we receive any significant adverse comment regarding the direct final rule, we will withdraw the direct final rule within 30 days after the comment period ends and proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment rulemaking procedures under the Administrative Procedure Act (APA) (5 U.S.C. 552a *et seq*). The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-

comment process in accordance with section 553 of the APA (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

II. What Is the Background of the Rule?

On October 26, 2002, MDUFMA (Public Law 107–250), amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 510(o) (21 U.S.C. 360(o)), which provided new regulatory requirements for reprocessed SUDs. The new provision requires validation data to be included in the premarket notification (510(k)) for certain reprocessed SUDs, to ensure that reprocessed SUDs are substantially equivalent to predicate devices. The validation data includes cleaning and sterilization data, and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed.

Before enactment of the new law, a manufacturer of a reprocessed SUD was required to obtain premarket approval or premarket clearance for the device, unless the device was exempt from premarket submission requirements. Under MDUFMA, some previously exempt reprocessed SUDs are no longer exempt from premarket notification requirements. Manufacturers of these identified devices were required to submit 510(k)s that included validation data specified by FDA. Reprocessors of certain SUDs already subject to cleared 510(k)s were also required to submit the validation data specified by the agency.

A. Definitions

Under section 201(ll)(2)(A) of the act (21 U.S.C. 321(ll)(2)(A)), a reprocessed SUD is defined as an ''original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.'' FDA is amending § 807.3 (21 CFR 807.3) by adding paragraph (t) to incorporate this definition into the regulations.

Reprocessed SUDs are divided into three groups: (1) Critical, (2) semicritical, and (3) noncritical. The first two categories are set forth in the act and all three reflect a categorization scheme recognized in the industry (Ref. 1). In the **Federal Register** of April 30, 2003 (68 FR 23139), FDA describes in more detail the development of this scheme and its use in the implementation of section 510(o) of the act. The act defines critical and semicritical reprocessed single use devices at section 201(mm) as amended by MDUFMA. FDA defined noncritical devices in the **Federal Register** of April 30, 2003. The definitions are as follows:

- A critical reprocessed SUD is intended to contact normally sterile tissue or body spaces during use.
- A semicritical reprocessed SUD is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.
- A noncritical reprocessed SUD is intended to make topical contact and not penetrate intact skin.

B. Critical and Semicritical Reprocessed SUDs Previously Exempt from Premarket Notification

MDUFMA required FDA to review the critical and semicritical reprocessed SUDs that were previously exempt from premarket notification requirements and determine which of these devices required premarket notification to ensure their substantial equivalence to predicate devices. Under MDUFMA, FDA was required to identify in a **Federal Register** notice those critical reprocessed SUDs whose exemption from premarket notification would be terminated and for which FDA determined that validation data, as specified under MDUFMA, was necessary in a 510(k). FDA published a list of these devices on April 30, 2003. According to the law, manufacturers of the devices whose exemptions from premarket notification were terminated were required to submit 510(k)s that included validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in § 807.87 (21 CFR 807.87), within 15 months of publication of the notice or no longer market their devices.

In accordance with section 510(o) of the act, FDA must revise the list of devices subject to this requirement as appropriate. In the **Federal Register** of June 26, 2003 (68 FR 38071), FDA recategorized nine device types from semicritical to critical, and added nonelectric gastroenterology-urology biopsy forceps to the list of critical reprocessed SUDs whose exemption from premarket notification requirements was being terminated. In the **Federal Register** of September 29, 2005 (70 FR 56911), FDA announced that it was adding devices to the list of critical reprocessed SUDs whose 510(k) exemption is terminated and for which validation data is necessary.

By April 26, 2004, FDA was required to identify in a **Federal Register** notice those semicritical reprocessed SUDs whose exemption from premarket notification would be terminated and for which FDA determined that validation data, as specified under MDUFMA, was necessary in a 510(k). FDA published this list in the **Federal Register** of April 13, 2004 (69 FR 19433). As discussed previously in this document, manufacturers of the devices whose exemptions from premarket notification were terminated were required to submit 510(k)s that included validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in § 807.87, within 15 months of publication of the notice or no longer market their devices. In accordance with section 510(o) of the act, FDA must revise the list of devices subject to this requirement as appropriate.

C. Reprocessed SUDs Already Subject to Premarket Notification Requirements

MDUFMA also required FDA to review the types of reprocessed SUDs already subject to premarket notification requirements and to identify which of these devices required the submission of validation data to ensure their substantial equivalence to predicate devices. FDA published a list of these devices in the **Federal Register** of April 30, 2003. As described previously in this document, FDA must revise the list of devices subject to this requirement as appropriate. In the **Federal Register** of September 29, 2005, FDA announced that it was adding laparoscopic and endoscopic electrosurgical accessories to this list of reprocessed SUDs already subject to premarket notification.

For devices identified on this list that had already been cleared through the 510(k) process, manufacturers were required to submit validation data regarding cleaning, sterilization, and functional performance within 9 months of publication of the list or no longer market their devices.

For devices on this list that were not yet cleared through the 510(k) process, manufacturers were required to submit

510(k)s with validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements identified in § 807.87.

III. What Does This Proposed Rule Do?

As described previously in this document, we have already taken actions required under section 510(o) of the act. This proposed rule would codify these actions, including revocations of exemption from premarket notification for SUDs and the requirement to submit validation data, and add definitions based on the statute to 21 CFR part 807. The proposed rule does not make any substantive changes to existing requirements. We have included a detailed description of specific changes in the rule in the preamble to the direct final rule, published elsewhere in this issue of the **Federal Register**.

FDA has made available previously a guidance document on the submission of validation data entitled ''Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices'' (69 FR 30943, June 1, 2004). This guidance document may be accessed on the Internet at *http://www.fda.gov/cdrh/ode/guidance/1216.html*.

IV. What Is the Legal Authority for This Proposed Rule?

This proposed rule is authorized by sections 201, 301, 501, 502, 510, 513, 515, 519, 520, 701, 704, 801, and 903 of the act and sections 264 and 271 of the Public Health Service Act (21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264 and 271) .

V. What Is the Environmental Impact of This Proposed Rule?

We have determined under 21 CFR 25.30(h) and 25.34(a) 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.

VI. What Is the Economic Impact of This Proposed Rule?

We have examined the impacts of the rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule will not change any existing requirements or impose any new requirements, we certify that the proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $118 million, using the most current (2004) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. How Does the Paperwork Reduction Act of 1995 Apply to This Rule?

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the proposed rule have been approved by OMB in accordance with the PRA under the regulations governing premarket notifications (21 CFR part 807, OMB control number 0910–0120).

VIII. What Are the Federalism Impacts of This Proposed Rule?

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. How Do You Submit Comments on This Proposed Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposed rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. What Is the Reference for This Rule?

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 am. and 4 pm., Monday through Friday.

1. Spaulding, E. H., ''The Role of Chemical Disinfection in the Prevention of Nonsocomial Infections.'' Edited by P. S. Brachman and T. C. Eickof, Proceedings of International Conference on Nonsocomial Infections, 1970, American Hospital Association, Chicago, 254–274, 1971.

List of Subjects

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

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

Medical devices.

21 CFR Part 886

Medical devices, Opthalmic 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, it is proposed that 21 CFR parts 807, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, and 892 be amended as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

1. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271

2. Section 807.3 is amended by adding new paragraphs (t), (u), and (v) to read as follows:

§ 807.3 Definitions.

* * * * *

(t) A single use device (SUD) means a device that is intended for one use or on a single patient during a single procedure.

(u) A reprocessed SUD is an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed SUD shall result in a device that is reprocessed within the meaning of this definition.

(v) Validation data for the purposes of this part means cleaning and sterilization data, and functional performance data demonstrating that an SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

3. Section 807.87 is amended by redesignating paragraphs (h), (i), (j), (k), and (l) as paragraphs (i), (j), (k), (l), and (m), respectively, and by adding new paragraph (h) to read as follows:

§ 807.87 Information required in a premarket notification submission.

* * * * *

(h) If the device is a reprocessed SUD that FDA has identified as requiring validation data, the premarket notification submission must include validation data as defined in § 807.3(v).

* * * * *

PART 868—ANESTHESIOLOGY DEVICES

4. The authority citation for 21 CFR part 868 continues to read as follows:

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

5. Section 868.5150 is amended by revising paragraph (b) to read as follows:

§ 868.5150 Anesthesia conduction needle.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an anesthetic conduction needle (with/without introducer) or a short term spinal needle and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

6. Section 868.5730 is amended by revising paragraph (b) to read as follows:

§ 868.5730 Tracheal tube.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

7. Section 868.5905 is amended by revising paragraph (b) to read as follows:

§ 868.5905 Noncontinuous ventilator (IPPB).

* * * * *

(b) *Classification.* Class II (special controls). If the device is a noncontinuous ventilator (respirator) mask that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

8. Section 868.6810 is amended by revising paragraph (b) to read as follows:

§ 868.6810 Tracheobronchial suction catheter.

* * * * *

(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 § 868.9. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

PART 870—CARDIOVASCULAR DEVICES

9. The authority citation for 21 CFR part 870 continues to read as follows:

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

10. Section 870.1200 is amended by revising paragraph (b) to read as follows:

§ 870.1200 Diagnostic intravascular catheter.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an angiography catheter that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

11. Section 870.1220 is amended by revising paragraph (b) to read as follows:

§ 870.1220 Electrode recording catheter or electrode recording probe.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an electrode recording catheter or intracardiac mapping catheter that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

12. Section 870.1230 is amended by revising paragraph (b) to read as follows:

§ 870.1230 Fiberoptic oximeter catheter.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

13. Section 870.1280 is amended by revising paragraph (b) to read as follows:

§ 870.1280 Steerable catheter.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

14. Section 870.1290 is amended by revising paragraph (b) to read as follows:

§ 870.1290 Steerable catheter control system.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

15. Section 870.1330 is amended by revising paragraph (b) to read as follows:

§ 870.1330 Catheter guide wire.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

16. Section 870.1390 is amended by revising paragraph (b) to read as follows:

§ 870.1390 Trocar.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a

cardiovascular trocar that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

17. Section 870.1650 is amended by revising paragraph (b) to read as follows:

§ 870.1650 Angiographic injector and syringe.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

18. Section 870.1670 is amended by revising paragraph (b) to read as follows:

§ 870.1670 Syringe actuator for an injector.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

19. Section 870.2700 is amended by revising paragraph (b) to read as follows:

§ 870.2700 Oximeter.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a tissue saturation oximeter or an oximeter and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

20. Section 870.3535 is amended by revising paragraph (b) to read as follows:

§ 870.3535 Intra-aortic balloon and control system.

* * * * *

(b) *Classification.* Class III (premarket approval). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

* * * * *

21. Section 870.4450 is amended by revising paragraph (b) to read as follows:

§ 870.4450 Vascular clamp.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

22. Section 870.4500 is amended by revising paragraph (b) to read as follows:

§ 870.4500 Cardiovascular surgical instruments.

* * * * *

(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 § 870.9. If the device is a noncompression heart stabilizer that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

23. Section 870.4885 is amended by revising paragraph (b) to read as follows:

§ 870.4885 External vein stripper.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 872—DENTAL DEVICES

24. The authority citation for 21 CFR part 872 continues to read as follows:

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

25. Section 872.3240 is amended by revising paragraph (b) to read as follows:

§ 872.3240 Dental bur.

* * * * *

(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 § 872.9. If the device is a dental diamond coated bur that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification submission that includes validation data as described in § 807.3(v).

26. Section 872.4535 is amended by revising paragraph (b) to read as follows:

§ 872.4535 Dental diamond 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 § 872.9. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

27. Section 872.4730 is amended by revising paragraph (b) to read as follows:

§ 872.4730 Dental injecting needle.

* * * * *

(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 § 872.9. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

28. Section 872.5410 is amended by revising paragraph (b) to read as follows:

§ 872.5410 Orthodontic appliance and accessories.

* * * * *

(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 § 872.9. If the device is a orthodontic metal bracket that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

29. Section 872.5470 is amended by revising paragraph (b) to read as follows:

§ 872.5470 Orthodontic plastic bracket.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

PART 874—EAR, NOSE, AND THROAT DEVICES

30. The authority citation for 21 CFR part 874 continues to read as follows:

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

31. Section 874.4140 is amended by revising paragraph (b) to read as follows:

§ 874.4140 Ear, nose, and throat bur.

* * * * *

(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 § 874.9. If the device is an ear, nose, and throat (ENT) high speed microdebrider or an ENT diamond coated bur and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

32. Section 874.4420 is amended by revising paragraph (b) to read as follows:

§ 874.4420 Ear, nose, and throat manual surgical 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 § 874.9. If the device is a laryngeal, sinus, or tracheal trocar that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

33. Section 874.4680 is amended by revising paragraph (b) to read as follows:

§ 874.4680 Bronchoscope (flexible or rigid) and accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a bronchoscope (nonrigid) biopsy forceps that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

34. The authority citation for 21 CFR part 876 continues to read as follows:

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

35. Section 876.1075 is amended by revising paragraph (b) to read as follows:

§ 876.1075 Gastroenterology-urology biopsy instrument.

* * * * *

(b) *Classification.* (1) Class II (special controls). If the device is a gastroenterology-urology (G–U) biopsy needle and needle set or a biopsy instrument and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

(2) Class I (general controls) for the biopsy forceps cover and the non-electric biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. If the device is a non-electric biopsy forceps that is a reprocessed SUD as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

36. Section 876.1500 is amended by revising paragraph (b)(1) to read as follows:

§ 876.1500 Endoscope and accessories.

* * * * *

(b) *Classification.* (1) Class II (special controls). If the device is an endoscopic needle, an endoilluminator, a general and plastic surgery laparoscope, or a spring-loaded pneumoperitoneum needle and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

* * * * *

37. Section 876.4300 is amended by revising paragraph (b) to read as follows:

§ 876.4300 Endoscopic electrosurgical unit and accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an active urological electrosurgical electrode, a flexible suction coagulator electrode, an electric biopsy forceps, a flexible snare, or an endoscopic (with or without accessories) electrosurgical unit that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

38. Section 876.4680 is amended by revising paragraph (b) to read as follows:

§ 876.4680 Ureteral stone dislodger.

* * * * *

(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. If the device is a flexible and basket stone dislodger that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

39. Section 876.5010 is amended by revising paragraph (b) to read as follows:

§ 876.5010 Biliary catheter 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 § 876.9. If the device is a biliary catheter that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

40. Section 876.5540 is amended in paragraph (b)(3) to read as follows:

§ 876.5540 Blood access device and accessories.

* * * * *

(b) * * *

(3) Class II (special controls) for accessories for both the implanted and the nonimplanted blood access devices not listed in paragraph (b)(4) of this section. If the device is a single needle dialysis set (coaxial flow) or fistula needle and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

* * * * *

41. Section 876.5820 is amended by revising paragraph (b)(1) to read as follows:

§ 876.5820 Hemodialysis system and accessories.

* * * * *

(b) *Classification.* (1) Class II (special controls) (for hemodialysis systems and all accessories directly associated with the extracorporeal blood system and the dialysate delivery system). If the device is a single needle dialysis set with uni-directional pump that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

* * * * *

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

42. The authority citation for 21 CFR part 878 continues to read as follows:

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

43. Section 878.4200 is amended by revising paragraph (b) to read as follows:

§ 878.4200 Introduction/drainage catheter and accessories.

* * * * *

(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 § 878.9. If the device is a catheter needle that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

44. Section 878.4300 is amended by revising paragraph (b) to read as follows:

§ 878.4300 Implantable clip.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

45. Section 878.4400 is amended by revising paragraph (b) to read as follows:

§ 878.4400 Electrosurgical cutting and coagulation device and accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an endoscopic or laparoscopic electrosurgical accessory that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

46. Section 878.4750 is amended by revising paragraph (b) to read as follows:

§ 878.4750 Implantable staple.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

47. Section 878.4800 is amended by revising paragraph (b) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

* * * * *

(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 § 878.9. If the device is a percutaneous biopsy device, a gastroenterology-urology needle, a cardiovascular biopsy needle, or an aspiration and injection needle and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

48. The authority citation for 21 CFR part 880 continues to read as follows:

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

49. Section 880.5570 is amended by revising paragraph (b) to read as follows:

§ 880.5570 Hypodermic single lumen needle.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

50. Section 880.5860 is amended by revising paragraph (b) to read as follows:

§ 880.5860 Piston syringe.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 882—NEUROLOGICAL DEVICES

51. The authority citation for 21 CFR part 882 continues to read as follows:

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

52. Section 882.4190 is amended by revising paragraph (b) to read as follows:

§ 882.4190 Clip forming/cutting 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. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

53. Section 882.4300 is amended by revising paragraph (b) to read as follows:

§ 882.4300 Manual cranial drills, burrs, trephines, and accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

54. Section 882.4305 is amended by revising paragraph (b) to read as follows:

§ 882.4305 Powered compound cranial drills, burrs, trephines, and their accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

55. Section 882.4310 is amended by revising paragraph (b) to read as follows:

§ 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

56. The authority citation for 21 CFR part 884 continues to read as follows:

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

57. Section 884.1720 is amended by revising paragraph (b)(1) to read as follows:

§ 884.1720 Gynecologic laparoscope and accessories.

* * * * *

(b) (1) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

* * * * *

58. Section 884.1730 is amended by revising paragraph (b)(2) to read as follows:

§ 884.1730 Laparoscopic insufflator.

* * * * *

(b) * * *

(2) Class I for tubing and tubing/filter kits which include accessory instruments that are not used to effect intra-abdominal insufflation (pneumoperitoneum). The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

59. Section 884.4530 is amended by revising paragraph (b)(2) to read as follows:

§ 884.4530 Obstetric-gynecologic specialized manual instrument.

* * * * *

(b) * * *

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, intrauterine device (IUD) remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9. If the device is a gynecological biopsy forceps that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

60. Section 884.6100 is amended by revising paragraph (b) to read as follows:

§ 884.6100 Assisted reproduction needles.

* * * * *

(b) *Classification*. Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

PART 886—OPTHALMIC DEVICES

61. The authority citation for 21 CFR part 886 continues to read as follows:

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

62. Section 886.4350 is amended by revising paragraph (b) to read as follows:

§ 886.4350 Manual ophthalmic surgical 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 § 886.9. If the device is an ophthalmic knife that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

63. Section 886.4370 is amended by revising paragraph (b) to read as follows:

§ 886.4370 Keratome.

* * * * *

(b) *Classification*. Class I (general controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

64. Section 886.4670 is amended by revising paragraph (b) to read as follows:

§ 886.4670 Phacofragmentation system.

* * * * *

(b) *Classification*. Class II (special controls). If the device is a phacoemulsification needle that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 892—RADIOLOGY DEVICES

65. The authority citation for 21 CFR part 892 continues to read as follows:

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

66. Section 892.5730 is amended by revising paragraph (b) to read as follows:

§ 892.5730 Radionuclide brachytherapy source.

* * * * *

(b) *Classification*. Class II (special controls). If the device is an isotope needle that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

Dated: September 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–8165 Filed 9–22–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 06–036]

RIN 1625–AA00

Safety Zone; Red Bull Air Show Practice, San Francisco Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes a safety zone to be used to keep spectator vessels out of the path and away from the area directly below participating aircraft during the fleet week air show practice in order to ensure the safety of event participants and spectators.

DATES: Comments and related material must reach the Coast Guard on or before October 10, 2006.

ADDRESSES: You may mail comments and related material to the Waterways Safety Branch, U.S. Coast Guard Sector San Francisco, 1 Yerba Buena Island, San Francisco, California 94130. The Waterways Safety Branch maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the Waterways Safety Branch between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ensign Erin Bastick, U.S. Coast Guard Sector San Francisco, at (415) 556–2950 or Sector San Francisco 24 hour Command Center at (415) 399–3547.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (COTP San Francisco Bay 06–036), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may