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Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2021–27406 Filed 12–16–21; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2021–N–0857]

Medical Devices; General and Plastic Surgery Devices; Classification of the Manual Percutaneous Surgical Set Assembled in the Abdomen

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the manual percutaneous surgical set assembled in the abdomen into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the manual percutaneous surgical set assembled in the abdomen's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 17, 2021. The classification was applicable on April 30, 2012.

FOR FURTHER INFORMATION CONTACT: Cal Rabang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4633, Silver Spring, MD 20993–0002, 301–796–6412, *Cal.Rabang@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the manual percutaneous surgical set assembled in the abdomen as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application (PMA) to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on August 26, 2011, finding the Percutaneous Surgical Set with 5mm or 10mm Attachments not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On September 21, 2011, FDA received Ethicon Endo-Surgery, Inc.'s request for De Novo classification of the Percutaneous Surgical Set with 5mm or 10mm Attachments. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 30, 2012, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 878.4805.[1] We have named the

[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

generic type of device manual percutaneous surgical set assembled in the abdomen, and it is identified as a prescription device consisting of a percutaneous surgical set used as a means to penetrate soft tissue to access certain areas of the abdomen. The device's effectors or attachments are provided separately from the percutaneous shaft and are introduced to the site via a traditional conduit such as a trocar. The attachment or effectors are connected to the shaft once the tip of the shaft is inside the abdomen. Once inside the abdomen, the surgical set is used to grasp, hold, and manipulate soft tissues. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in 21 CFR parts 868 through 892.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—MANUAL PERCUTANEOUS SURGICAL SET ASSEMBLED IN THE ABDOMEN RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Device failure	Non-clinical performance testing, Sterilization validation, and Shelf life testing.
User error	Non-clinical performance testing, Simulated use testing, and Labeling.
Abdominal cavity damage	Non-clinical performance testing, Simulated use testing, and Labeling.
Infection	Sterilization validation and Shelf life testing.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, manual percutaneous surgical sets assembled in the abdomen are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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 the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; 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 part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

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

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

■ 2. Add § 878.4805 to subpart E to read as follows:

§ 878.4805 Manual percutaneous surgical set assembled in the abdomen.

(a) *Identification.* A manual percutaneous surgical set assembled in the abdomen is a prescription device consisting of a percutaneous surgical set used as a means to penetrate soft tissue to access certain areas of the abdomen. The device's effectors or attachments are provided separately from the percutaneous shaft and are introduced to the site via a traditional conduit such as a trocar. The attachment or effectors are connected to the shaft once the tip of the shaft is inside the abdomen. Once inside the abdomen, the surgical set is used to grasp, hold, and manipulate soft tissues. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892 of this chapter.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Performance data must demonstrate the sterility of patient-contacting components of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the requested shelf life.

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following

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.

performance characteristics must be tested:

(i) Dimensional verification testing must be conducted.

(ii) Force verification testing must be conducted. The force testing must demonstrate the forces necessary to insert and operate each component of the device during use as intended.

(iii) Functional verification testing of the device components must be conducted.

(5) Simulated use testing in an anatomically relevant animal model must demonstrate the device's ability to penetrate soft tissue, be assembled in situ, and to grasp, hold and manipulate soft tissues in the intended treatment area.

(6) The labeling must include the following:

(i) Instructions for use, including detailed instructions for instrument assembly, disassembly, and removal; and

(ii) A shelf life.

Dated: December 10, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27317 Filed 12–16–21; 8:45 am]

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DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Chapter VII

[Docket ID: USAF–2021–HQ–0001]

RIN 0701–AA81

Appointment to the Air Force Academy

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Final rule.

SUMMARY: This final rule removes the regulation concerning how the Department of the Air Force appoints individuals to the United States Air Force Academy. The part is outdated, contains internal guidance, reiterates statutory law, and is otherwise subject to the military function exemption to rulemaking. Applicants to the Air Force Academy are individually provided with any relevant entrance information and the current policy is publicly available on the United States Air Force Academy's website. Therefore, the part is unnecessary and can be removed from the Code of Federal Regulations (CFR).

DATES: This rule is effective on December 17, 2021.

FOR FURTHER INFORMATION CONTACT: Laura Megan-Posch at 703–697–4370.

SUPPLEMENTARY INFORMATION: This final rule removes 32 CFR part 901, ''Appointment to the United States Air Force Academy,'' which was originally published on June 26, 1986 (51 FR 23221), and has not since been updated. Part 901 is outdated, contains internal guidance, reiterates statutory law, and is otherwise subject to the military function exemption to rulemaking. Current policy is provided individually to applicants and is contained in Air Force Manual 36–2032, Military Recruiting and Accessions, September 27, 2019 (available at *https://static.e-publishing.af.mil/production/1/af_a1/publication/afman36-2032/afman36-2032.pdf*). Accordingly, this part is unnecessary and can be removed from the CFR. It has been determined that publication of this CFR part removal for public comment is impracticable and contrary to the public interest because it is based on removing outdated and unnecessary content. This rule is not significant under Executive Order 12866, Sec 3, ''Regulatory Planning and Review.''

The Under Secretary of the Air Force, Ms. Gina Ortiz Jones, having reviewed and approved this document, is delegating the authority to electronically sign this document to Mr. Tommy W. Lee, who is the Air Force Federal Register Liaison Officer, for purposes of publication in the **Federal Register**.

List of Subjects in 32 CFR Part 901

Military academies, Reporting and recordkeeping requirements.

CHAPTER VII—DEPARTMENT OF THE AIR FORCE

SUBCHAPTER K—[REMOVED AND RESERVED]

■ Accordingly, by the authority of 5 U.S.C. 301, subchapter K of chapter VII of 32 CFR, consisting of part 901, is removed and reserved.

Tommy W. Lee,

Air Force Federal Register Liaison Officer.

[FR Doc. 2021–27304 Filed 12–16–21; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0906]

RIN 1625–AA00

Safety Zone; Potomac River, Between Charles County, MD and King George County, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of the Potomac River. This action is necessary to provide for the safety of persons, and the marine environment from the potential safety hazards associated with construction operations at the new Governor Harry W. Nice/Senator Thomas ''Mac'' Middleton Memorial (US–301) Bridge, which will occur from 7 a.m. on January 3, 2022, through 8 p.m. on January 15, 2022. This rule will prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port, Maryland-National Capital Region or a designated representative.

DATES: This rule is effective without actual notice from December 17, 2021 through January 15, 2022. For the purposes of enforcement, actual notice will be issued from December 13, 2021 until December 17, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0906 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Ron Houck, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
§ Section
TFR Temporary Final Rule
U.S.C. United States Code

II. Background Information and Regulatory History

On December 9, 2021, Skanska-Corman-McLean, Joint Venture, notified