level because of your impairment or because of the removal of special conditions that took into account your impairment and permitted you to work.

* * * * *

■ 9. Amend § 416.999a by revising paragraph (a)(4)(i) and (c)(2) to read as follows:

§ 416.999a Who is eligible for expedited reinstatement?

(a) * * *

(4) * * *

(i) You are not able or become unable to do substantial gainful activity because of your medical condition as determined under paragraph (c) of this section.

* * * * *

(c) * * *

(2) You are not able or become unable to do substantial gainful activity in the month you file your request for reinstatement; and

* * * * *

[FR Doc. 2016–24873 Filed 10–14–16; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2016–N–2766]

Medical Devices; Cardiovascular Devices; Classification of the Apical Closure Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the apical closure device into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the apical closure device's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective October 17, 2016. The classification was applicable on July 27, 2016.

FOR FURTHER INFORMATION CONTACT: Jennifer Piselli, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 1561, Silver Spring, MD, 20993–0002, 240–402–6646, *jennifer.piselli@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On June 25, 2015, Micro Interventional Devices, Inc. submitted a request for classification of the Permaseal Device under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies 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 to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on July 27, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 870.4510.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an apical closure device will need to comply with the special controls named in this final administrative order.

The device is assigned the generic name apical closure device, and it is identified as a prescription device consisting of a delivery system and implant component that is used for soft tissue approximation of cardiac apical tissue during transcatheter valve replacement procedures.

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—APICAL CLOSURE DEVICE RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measure
Infection	Sterilization Validation. Shelf Life Testing. Labeling.
Adverse Tissue Reaction	Biocompatibility Evaluation. In vivo Performance Testing.
Bleeding	Non-clinical Performance Testing.
▪ At ventricular puncture or anchor deployment sites	In vivo Performance Testing. Labeling.
Tissue Damage	Non-clinical Performance Testing.
▪ Apical tearing	In vivo Performance Testing.
▪ Myocardial tearing (local or diffuse)	Labeling. Training.
New Hypokinesia or Akinesis of Apex	In vivo Performance Testing. Labeling.
Thromboemboli and Full Thickness Injury	In vivo Performance Testing. Labeling. Training.
Pericardial Tamponade	In vivo Performance Testing. Labeling.

FDA believes that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

Apical closure devices are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109 *Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the apical closure device they intend to market.

II. 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.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. 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. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, 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 870

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 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 is revised to read as follows:

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

■ 2. Add § 870.4510 to subpart E to read as follows:

§ 870.4510 Apical closure device.

(a) *Identification.* An apical closure device is a prescription device consisting of a delivery system and implant component that is used for soft tissue approximation of cardiac apical tissue during transcatheter valve replacement procedures.

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

(1) The patient contacting materials must be evaluated to be biocompatible.

(2) Performance data must validate the sterility of the 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 labeled shelf life.

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

(i) Consistent and reliable implant deployment;

(ii) Assessment of implant pull-out force; and

(iii) Sheath size compatibility with implant.

(5) In vivo evaluation of the device must demonstrate device performance, including device operation resulting in closure of the myocardial wound.

(6) Labeling must include the following:

(i) Detailed information explaining how the device operates;

(ii) Sheath size that device can accommodate;

(iii) Identification of the minimum myocardial wall thickness to ensure optimal device function; and

(iv) A shelf life.

Dated: October 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25002 Filed 10–14–16; 8:45 am]

BILLING CODE 4164–01–P