ACTION: Direct final rule; confirmation of effective date.

SUMMARY: On February 14, 2022, the Department of Labor (Department) concurrently published both a direct final rule (DFR) and proposed rule putting forth guidance on priority service, durational limits, and State Plan submissions regarding a State's Senior Community Service Employment Program, or SCSEP. Because the Department did not receive any significant adverse comments within the scope of the rulemaking, the Department is implementing the DFR as published.

DATES: As of May 6, 2022, the Department is confirming the effective date of the rule published February 14, 2022 at 87 FR 8186 as April 15, 2022.

FOR FURTHER INFORMATION CONTACT: Steven Rietzke, Chief, Division of National Programs, Tools and Technical Assistance, Office of Workforce Investment, at 202–693–3980 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The DFR published at 87 FR 8186 on February 14, 2022, became effective on April 15, 2022. In the DFR, the Department stated that the DFR would become effective April 15, 2022 without further action, unless significant adverse comments were submitted by March 16, 2022 (the end of the public comment period), and the Department would publish a timely withdrawal of the proposed rule. In the same issue of the **Federal Register** in which this notice is published, the Department is publishing a withdrawal of the proposed rule, which was also published on February 14, 2022.

The Department received seven comments on this rulemaking. Several of these comments were supportive of the provisions this rulemaking proposed to implement. While other comments could be characterized as negative or adverse, none of those comments were significant or within the scope of this rulemaking. One commenter was opposed to the time limit; however, that time limit is set forth in the Supporting Older Americans Act of 2020, and is, therefore, a statutory requirement beyond the purview of the rulemaking. The remaining comments were outside the scope of the rulemaking. The comments are publicly available as part of the rulemaking docket at *https://www.regulations.gov/docket/ETA-2022-0002/comments.*

The Department has determined that none of the adverse comments are significant and within the scope of the rulemaking. Therefore, the DFR published at 87 FR 8186 on February 14, 2022, became effective on April 15, 2022.

Angela Hanks,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2022–09491 Filed 5–5–22; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2022–N–0289]

Medical Devices; Cardiovascular Devices; Classification of the Reverse Central Venous Recanalization System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the reverse central venous recanalization system 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 reverse central venous recanalization system'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 May 6, 2022. The classification was applicable on February 10, 2020.

FOR FURTHER INFORMATION CONTACT: Finn Donaldson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2568, Silver Spring, MD 20993–0002, 301–796–9579, *Finn.Donaldson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the reverse central venous recanalization system 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, in part by placing the device into a lower device class than the automatic class III assignment.

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 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. 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) of the FD&C Act.

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.

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 section 513(f)(2)(B)(i) of the FD&C Act). 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 section 513(i) of the FD&C Act, 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 March 21, 2016, finding the Surfacer Inside-Out Access Catheter System 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 August 15, 2019, FDA received Bluegrass Vascular Technologies, Inc.'s request for De Novo classification of the Surfacer Inside-Out Access Catheter System. 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 February 10, 2020, 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 870.1342.[1] We have named the generic type of device reverse central venous recanalization system, and it is identified as a prescription device for obtaining central venous access to facilitate catheter insertion into the central venous system. Reverse recanalization involves the initiation of an access path from within the vein and then progressing to the skin for patients with upper body venous occlusions or other conditions that preclude central venous access by other methods.

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—REVERSE CENTRAL VENOUS RECANALIZATION SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Infection	Sterilization validation, Shelf life testing, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Embolization caused by component fracture	Clinical performance testing, and Non-clinical performance testing.
Death, bleeding, damage to non-target tissue and organs, blood vessel perforation or rupture, hematoma; or delays to therapy from failure to achieve central venous access.	Clinical performance testing, Non-clinical performance testing, and Labeling.

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. In order 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. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, reverse central venous recanalization systems 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 21 CFR part 860, subpart D, regarding De Novo classification 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 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:

[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.

PART 870—CARDIOVASCULAR DEVICES

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

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

■ 2. Add § 870.1342 to subpart B to read as follows:

§ 870.1342 Reverse central venous recanalization system.

(a) *Identification.* A reverse central venous recanalization system is a prescription device for obtaining central venous access to facilitate catheter insertion into the central venous system. Reverse recanalization involves the initiation of an access path from within the vein and then progressing to the skin for patients with upper body venous occlusions or other conditions that preclude central venous access by other methods.

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

(1) Clinical performance testing must fulfill the following:

(i) Demonstrate the ability to safely deliver, deploy, and remove the device; and

(ii) Evaluate all adverse events including death, bleeding, damage to non-target tissue and organs, blood vessel perforation or rupture, and hematoma.

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

(i) Simulated-use testing in a clinically relevant bench anatomic model to assess the delivery, deployment, and retrieval of the system;

(ii) Compatibility with other devices labeled for use with the device;

(iii) Tensile strengths of joints and components;

(iv) Kink resistance of system components;

(v) Radiopacity of components used to monitor procedure under fluoroscopy;

(vi) Characterization and verification of all dimensions; and

(vii) Leakage of air or fluid.

(3) All patient contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

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

(6) Labeling for the device must include:

(i) Instructions for use, including a description of compatible devices;

(ii) A detailed summary of the clinical testing conducted and;

(iii) Shelf life and storage conditions.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09745 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2022–N–0141]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Magnetically Maneuvered Capsule Endoscopy System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the magnetically maneuvered capsule endoscopy system 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 magnetically maneuvered capsule endoscopy system'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 May 6, 2022. The classification was applicable on May 22, 2020.

FOR FURTHER INFORMATION CONTACT: Stephanie Cole, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2536, Silver Spring, MD 20993–0002, 301–796–8587, *Stephanie.Cole@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the magnetically maneuvered capsule endoscopy system 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, in part by placing the device into a lower device class than the automatic class III assignment.

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 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. 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) of the FD&C Act.

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