determine the arithmetic mean, unless the employer provides an acceptable survey. The NPC shall determine the wage in accordance with secs. 212(n) and 212(t) of the INA. If an acceptable employer-provided wage survey provides a median and does not provide an arithmetic mean, the median shall be the prevailing wage applicable to the employer's job opportunity. In making a PWD, the Chicago NPC will follow 20 CFR 656.40 and other administrative guidelines or regulations issued by ETA. The Chicago NPC shall specify the validity period of the PWD, which in no event shall be for less than 90 days or more than 1 year from the date of the determination.

* * * * *

(*2*) If the employer is unable to wait for the NPC to produce the requested prevailing wage for the occupation in question, or for the CO and/or the BALCA to issue a decision, the employer may rely on other legitimate sources of available wage information as set forth in paragraphs (a)(2)(ii)(B) and (C) of this section. If the employer later discovers, upon receipt of the PWD from the NPC, that the information relied upon produced a wage below the final PWD and the employer was paying the NPC-determined wage, no wage violation will be found if the employer retroactively compensates the H–2B nonimmigrant(s) for the difference between the wage paid and the prevailing wage, within 30 days of the employer's receipt of the PWD.

* * * * *

PART 656—LABOR CERTIFICATION PROCESS FOR PERMANENT EMPLOYMENT OF ALIENS IN THE UNITED STATES

■ 3. The authority citation for part 656 is revised to read as follows:

Authority: 8 U.S.C. 1182(a)(5)(A), 1182(p)(1); sec.122, Public Law 101–649, 109 Stat. 4978; and Title IV, Public Law 105–277, 112 Stat. 2681.

■ 4. Amend § 656.40 by revising paragraphs (a) and (b)(2) and (3) to read as follows:

§ 656.40 Determination of prevailing wage for labor certification purposes.

(a) *Application process.* The employer must request a PWD from the NPC, on a form or in a manner prescribed by OFLC. Prior to January 1, 2010, the SWA having jurisdiction over the area of intended employment shall continue to receive and process prevailing wage determination requests in accordance with the regulatory provisions and Department guidance in effect prior to January 1, 2009. On or after January 1, 2010, the NPC shall receive and process prevailing wage determination requests in accordance with these regulations and with Department guidance. The NPC will provide the employer with an appropriate prevailing wage rate. The NPC shall determine the wage in accordance with sec. 212(t) of the INA. Unless the employer chooses to appeal the center's PWD under § 656.41(a) of this part, it files the Application for Permanent Employment Certification either electronically or by mail with the processing center of jurisdiction and maintains the PWD in its files. The determination shall be submitted to the CO, if requested.

(b) * * *

(2) If the job opportunity is not covered by a CBA, the prevailing wage for labor certification purposes shall be the arithmetic mean, except as provided in paragraph (b)(3) of this section, of the wages of workers similarly employed in the area of intended employment. The wage component of the DOL Occupational Employment Statistics Survey shall be used to determine the arithmetic mean, unless the employer provides an acceptable survey under paragraph (g) of this section.

(3) If the employer provides a survey acceptable under paragraph (g) of this section that provides a median and does not provide an arithmetic mean, the prevailing wage applicable to the employer's job opportunity shall be the median of the wages of workers similarly employed in the area of intended employment.

* * * * *

Angela Hanks,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2021–26660 Filed 12–10–21; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2021–N–0575]

Medical Devices; Neurological Devices; Classification of the Temporary Coil Embolization Assist Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the temporary coil embolization assist device 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 temporary coil embolization assist device'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 13, 2021. The classification was applicable on April 24, 2019.

FOR FURTHER INFORMATION CONTACT: Xiaolin Zheng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4224, Silver Spring, MD 20993–0002, 301–796–2823, *Xiaolin.Zheng@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the temporary coil embolization assist device 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, 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 to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate 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 (21 U.S.C. 360c(a)(1)). Although the device was automatically 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 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 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 May 29, 2017, finding the Comaneci Embolization Assist Device not substantially equivalent to a predicate not subject to a premarket approval application. 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 28, 2017, Rapid-Medical Ltd. submitted a request for De Novo classification of the Comaneci Embolization Assist Device. 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 24, 2019, 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 882.5955.[1] We have named the generic type of device temporary coil embolization assist device, and it is identified as a prescription device intended for temporary use in the neurovasculature to mechanically assist in the embolization of intracranial aneurysms with embolic coils. The device is delivered into the neurovasculature with an endovascular approach. This device is not intended to be permanently implanted and is removed from the body when the procedure is completed.

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—TEMPORARY COIL EMBOLIZATION ASSIST DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Infection	Sterilization validation, Pyrogenicity testing, Shelf life testing, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Tissue or vessel damage:	Non-clinical performance testing, Clinical performance testing, and Labeling.
• Dissection	
• Perforation	
• Hemorrhage	
• Vasospasm	
Thromboembolic event	Non-clinical performance testing, Clinical performance testing, and Labeling.
Coils ensnarement	Non-clinical performance testing, 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. 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.

[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.

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

At the time of classification, temporary coil embolization assist devices 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 882

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 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

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

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

■ 2. Add § 882.5955 to subpart F to read as follows:

§ 882.5955 Temporary coil embolization assist device.

(a) *Identification.* A temporary coil embolization assist device is a prescription device intended for temporary use in the neurovasculature to mechanically assist in the embolization of intracranial aneurysms with embolic coils. The device is delivered into the neurovasculature with an endovascular approach. This device is not intended to be permanently implanted and is removed from the body when the procedure is completed.

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

(1) Clinical performance testing of the device must demonstrate the device performs as intended for temporary use as an endovascular device to assist in the coil embolization of intracranial aneurysms and must evaluate all adverse events, including tissue or vessel damage that could lead to dissection, perforation, hemorrhage, or vasospasm, thrombo-embolic events, and coil entanglement.

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

(3) Non-clinical performance testing must demonstrate the device performs as intended under anticipated conditions of use, including:

(i) Mechanical testing to demonstrate the device can withstand anticipated tensile, torsional, compressive, and tip deflection forces;

(ii) Mechanical testing to evaluate the radial forces exerted by the device;

(iii) Simulated use testing to demonstrate the device can be delivered to the target location in the neurovasculature and is compatible with embolic coils;

(iv) Dimensional verification testing;

(v) Radiopacity testing; and

(vi) Performance testing to evaluate the coating integrity and particulates under simulated use conditions.

(4) Animal testing under anticipated use conditions must evaluate all adverse events, including damage to vessels or tissues.

(5) Performance data must support the sterility and pyrogenicity of the device.

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

(7) The labeling must include:

(i) Instructions for use;

(ii) A detailed summary of the device technical parameters, including compatible delivery catheter dimensions and device sizing information;

(iii) A summary of the clinical testing results, including a detailed summary of the device- and procedure-related complications and adverse events; and

(iv) A shelf life.

Dated: December 6, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26926 Filed 12–10–21; 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–2021–N–0898]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Pressure Ulcer Management Tool

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the pressure ulcer management tool into class I. We are taking this action because we have determined that classifying the device into class I 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 13, 2021. The classification was applicable on December 20, 2018.

FOR FURTHER INFORMATION CONTACT: Gema Gonzalez, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2530, Silver Spring, MD 20993–0002, 301–796–6519, *Gema.Gonzalez@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the pressure ulcer management tool as class I, which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance