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

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 (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.

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 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

On April 3, 2017, FDA received Bruin Biometrics, LLC's request for De Novo classification of the SEM Scanner (Model 200). 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 I if general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(A)). After review of the information submitted in the request, we determined that the device can be classified into class I. FDA has determined that general controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 20, 2018, FDA issued an order to the requester classifying the device into class I. In this final order, FDA is codifying the classification of the device by adding 21 CFR 876.2100.[1] We have named the generic type of device pressure ulcer management tool, and it is identified as a prescription device intended for patients at risk of developing pressure ulcers. The device provides output that supports a user's decision to increase intervention. The device is an adjunct tool for pressure ulcer management that is not intended for detection or diagnostic purposes.

FDA has identified the following risks to health associated specifically with this type of device: Adverse tissue reaction, transmission of infection between patients, electromagnetic interference with patient monitoring equipment, and electrical shock. As previously stated, FDA believes general controls provide reasonable assurance of safety and effectiveness for this device type.

At the time of classification, pressure ulcer management tools 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.

Section 510(l)(1) of the FD&C Act provides that a device within a type that has been classified into class I under section 513 of the FD&C Act is exempt from premarket notification under section 510(k), unless the device is of substantial importance in preventing impairment of human health or presents a potentially unreasonable risk of illness or injury (21 U.S.C. 360(l)(1)). Devices within this type are exempt from the premarket notification requirements under section 510(k), subject to the limitations of exemptions in 21 CFR 876.9.

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 refers 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; and the collections of

[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.

information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120.

List of Subjects in 21 CFR Part 876

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 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

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

■ 2. Add § 876.2100 to subpart C to read as follows:

§ 876.2100 Pressure ulcer management tool.

(a) *Identification.* A pressure ulcer management tool is a prescription device intended for patients at risk of developing pressure ulcers. The device provides output that supports a user's decision to increase intervention. The device is an adjunct tool for pressure ulcer management that is not intended for detection or diagnostic purposes.

(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 § 876.9.

Dated: December 8, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26924 Filed 12–10–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 42

[Public Notice: 11460]

RIN 1400–AF20

Waiver of Personal Appearance and In-Person Oath Requirement for Certain Immigrant Visa Applicants Due to COVID–19

AGENCY: Department of State.

ACTION: Final rule and temporary final rule.

SUMMARY: This temporary final rule (TFR) provides flexibility for consular officers to waive the personal appearance of certain repeat immigrant visa applicants who were approved for an immigrant visa in the same classification and on the same basis as the current application on or after August 4, 2019. It also gives consular officers discretion to allow this subset of immigrant visa applicants to affirm the accuracy of the contents of their application without appearing in person before a consular officer. This TFR is effective immediately and expires after 24 months. The final rule portion of this document reinstates parts of the regulations with certain updates after the expiration of the TFR.

DATES: Amendments in instructions 2 and 3 in this temporary final rule are effective from December 13, 2021, through December 13, 2023. The amendment in instruction 4 is effective December 13, 2023.

FOR FURTHER INFORMATION CONTACT: Andrea Lage, Acting Senior Regulatory Coordinator, Visa Services Directorate, Bureau of Consular Affairs, Department of State; telephone (202) 485–7586, *VisaRegs@state.gov.*

SUPPLEMENTARY INFORMATION:

I. What changes to 22 CFR 42.62 and 42.67 does this TFR make?

The Department is temporarily authorizing consular officers, for 24 months, to waive, on a discretionary basis, the requirements in 22 CFR 42.62 and 42.67 that an immigrant visa applicant appear in person before and be interviewed by a consular officer for certain repeat immigrant visa applicants. This TFR applies to immigrant visa applicants who were issued a U.S. immigrant visa on or after August 4, 2019, who meet the following additional criteria: Individuals who would be eligible for a discretionary waiver of personal appearance and interview pursuant to this TFR must be seeking an immigrant visa in the same classification (or another classification as the result of automatic conversion due to the death or naturalization of the petitioner of the previously issued immigrant visa) and pursuant to the same approved petition as their previously approved application, and they must continue to qualify for the immigrant visa sought.

Under this TFR, the personal appearance and interview of certain applicants for an immigrant visa may be waived in the discretion of the consular officer, provided that the applicant is willing to affirm under penalty of perjury to the information provided on the Online Immigrant Visa and Alien Registration Application, Form DS–260 (or Form DS–230, Application for Immigrant Visa and Alien Registration if the consular officer authorizes the use of that form). The consular officer may communicate with the applicant by telephone or email, may request that the applicant provide additional information that the consular officer deems necessary, and may request the applicant to appear in person. If the applicant identifies the need to change responses to Form DS–260, the consular officer or other authorized consular staff can reopen the DS–260 for the applicant to make changes to that form and re-sign it under penalty of perjury.

This TFR will automatically expire 24 months after it takes effect. As the TFR is designed to help address the problem of applicants who are unable to travel due to the COVID–19 pandemic and who must meet specific time-limited criteria, this TFR will no longer be necessary as the pandemic becomes less acute and ordinary travel resumes. The Department believes that 24 months is sufficient to process the cases described.

Pursuant to section 222(a) of the Immigration and Nationality Act (INA), 8 U.S.C. 1202(a), every immigrant visa applicant must make an application in the form, manner, and place prescribed by regulation. Except as may otherwise be prescribed by regulations, every immigrant visa application must ''be signed by the applicant in the presence of the consular officer and verified by the oath of the applicant administered by the consular officer.'' INA 222(e), 8 U.S.C. 1202(e). Regulations further require immigrant visa applicants to be interviewed by a consular officer. 22 CFR 42.62(b). This TFR provides an exception to these personal appearance and interview requirements pursuant to INA 222(a) and (e), 8 U.S.C. 1202(a) and (e).

II. Why is the Department promulgating this TFR?

A. The COVID–19 Pandemic

On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency under section 319 of the Public Health Service Act (42 U.S.C. 247d) in response to COVID–19.[1] On March 13, 2020, then-President Trump declared a National Emergency concerning the COVID–19 outbreak to control the spread of the virus that causes COVID–19 in the United States.[2] That proclamation declared that the emergency began in the United States on March 1, 2020. In addition to the National Emergency, a variety of Presidential Proclamations have

[1] HHS, *Determination of Public Health Emergency,* 85 FR 7316 (Feb. 7, 2020).

[2] *Proclamation 9994 of March 13, 2020, Declaring a National Emergency Concerning the Coronavirus Disease (COVID–19) Outbreak,* 85 FR 15337 (Mar. 18, 2020).