§ 862.1676 Blood collection device for cell-free nucleic acids.

(a) *Identification.* A blood collection device for cell-free nucleic acids is a device intended for medical purposes to collect, store, transport, and handle blood specimens and to stabilize and isolate cell-free nucleic acid components prior to further testing.

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

(1) Design verification and validation documentation must include appropriate design inputs and design outputs that are essential for the proper functioning of the device for its intended use, including all of its indications for use, and must include the following:

(i) Documentation demonstrating that appropriate, as determined by FDA, measures are in place (*e.g.,* validated device design features and specifications) to ensure that users of blood collection device for cell-free nucleic acids devices are not exposed to undue risk of bloodborne pathogen exposure and operator injury during use of the device, including blood collection, transportation, and centrifugation processes.

(ii) Documentation demonstrating that appropriate, as determined by FDA, measures are in place (*e.g.,* validated device design features and specifications) to ensure that the device reproducibly and reliably collects, transports, stabilizes, and isolates cell-free nucleic acids of sufficient yield and quality suitable for downstream applications as appropriate for its intended use. At a minimum, these measures must include:

(A) Data demonstrating that blood samples collected in the device have reproducible cell-free nucleic acid yields that are suitable, as determined by FDA, for downstream testing as appropriate for the intended use, including estimates of within-lot, within-device, and lot-to-lot variability;

(B) Data demonstrating that cell-free nucleic acid yields isolated from blood specimens collected into the device do not add clinically significant bias to test results obtained using the downstream application(s) described in the intended use. For devices indicated for use with multiple downstream applications, data demonstrating acceptable performance for each type of claimed use or, alternatively, an appropriate, as determined by FDA, clinical justification for why such data are not needed;

(C) Data demonstrating that the device appropriately stabilizes cell-free nucleic acids after sample collection, during storage, and during transport over the claimed shelf life of the device;

(D) Data demonstrating that samples collected in the device have minimal levels of contamination with other types of nucleic acids present in cells or cellular components, and that these levels of contamination do not interfere with downstream testing;

(E) Data from analytical or clinical studies that demonstrate that, when used as intended, the device consistently draws a blood sample volume that is within the indicated fill range;

(F) Data from analytical or clinical studies that demonstrate that, when used as intended, cell-free nucleic acid yield, stability, and quality are not significantly impacted by interference due to other parts of the device (such as reduced or excess active ingredient) or specimen collection and processing procedures (such as hemolysis, centrifugation, or mixing of blood with anticoagulant or additives); and

(G) Data from analytical studies that demonstrate that the device is suitable for its intended use across all storage and sample handling conditions described in the device labeling, including device shelf life and shipping conditions (*e.g.,* temperature, humidity, duration).

(iii) A protocol, reviewed and determined acceptable by FDA, that specifies the verification and validation activities that will be performed for anticipated device modifications to reevaluate performance claims or performance specifications. This protocol must include a process for assessing whether a modification to technology, engineering, performance, materials, specifications, or indications for use, or any combination thereof, could significantly affect the safety or effectiveness of the device. The protocol must include assessment metrics, acceptance criteria, and analytical methods for the performance testing of changes.

Dated: September 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20254 Filed 9–6–24; 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–2024–N–4059]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Endoscopic Pancreatic Debridement Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the endoscopic pancreatic debridement 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 endoscopic pancreatic debridement 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 September 9, 2024. The classification was applicable on December 23, 2020.

FOR FURTHER INFORMATION CONTACT: Thelma Valdes, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2610, Silver Spring, MD 20993–0002, 301–796–9621, *Thelma.Valdes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the endoscopic pancreatic debridement device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

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 (see also part 860, subpart D (21 CFR part 860, subpart D)). 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).

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 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 16, 2020, FDA received Interscope, Inc's request for De Novo classification of the EndoRotor. 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 December 23, 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 876.4330.[1] We have named the generic type of device endoscopic pancreatic debridement device, and it is identified as a device intended to be inserted via an endoscope and placed through a cystogastrostomy fistula into the pancreatic cavity. It is intended for removal of necrotic tissue from a walled off pancreatic necrosis (WOPN) cavity.

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—ENDOSCOPIC PANCREATIC DEBRIDEMENT DEVICE RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation, and Pyrogenicity testing.
Infection	Sterilization validation, Pyrogenicity testing, Shelf life testing, Package integrity testing, and Labeling.
Electrical shock/electromagnetic interference	Electrical safety testing, and Electromagnetic compatibility testing.
Injury due to device malfunction or device misuse: • Injury to pancreas or other non-target tissue. • Stent dislodgement.	Clinical performance testing; Software validation, verification, and hazard analysis; Non-clinical performance testing; Labeling; and Training.
Injury due to procedure or device: • Hemorrhage/gastrointestinal (GI) bleeding. • Pneumoperitoneum. • Sepsis/multiorgan failure. • Morcellation of malignant tissue.	Clinical performance testing, Labeling, and Training.

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

[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.

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 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 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 § 876.4330 to subpart E to read as follows:

§ 876.4330 Endoscopic pancreatic debridement device.

(a) *Identification.* An endoscopic pancreatic debridement device is inserted via an endoscope and placed through a cystogastrostomy fistula into the pancreatic cavity. It is intended for removal of necrotic tissue from a walled off pancreatic necrosis (WOPN) cavity.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including evaluation of debridement of walled off pancreatic necrosis and all adverse events.

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

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

(4) The patient-contacting components of the device must be demonstrated to be non-pyrogenic.

(5) Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(6) 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) Testing of rotational speeds and vacuum pressure;

(ii) Functional testing including testing with all device components and the ability to torque the device; and

(iii) Functional testing in a relevant tissue model to demonstrate the ability to resect and remove tissue.

(7) Performance data must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(8) Software verification, validation, and hazard analysis must be performed.

(9) Training must be provided so that upon completion of the training program, the user can resect and remove tissue of interest while preserving non-target tissue.

(10) Labeling must include the following:

(i) A summary of the clinical performance testing conducted with the device;

(ii) Instructions for use, including the creation of a conduit for passage of endoscope and device into a walled off pancreatic necrotic cavity;

(iii) Unless clinical performance data demonstrates that it can be removed or modified, a boxed warning stating that the device should not be used in patients with known or suspected pancreatic cancer;

(iv) The recommended training for safe use of the device; and

(v) A shelf life for any sterile components.

Dated: September 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20248 Filed 9–6–24; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Sanctions Regulations Web General License 5P

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general license.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing one general license (GL) issued pursuant to the Venezuela Sanctions Regulations: GL 5P, which was previously made available on OFAC's website.

DATES: GL 5P was issued on August 12, 2024. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov.*

Background

On August 12, 2024, OFAC issued GL 5P to authorize certain transactions otherwise prohibited by the Venezuela Sanctions Regulations (VSR), 31 CFR part 591. GL 5P was made available on OFAC's website (*https://ofac.treasury.gov*) when it was issued. GL 5P supersedes GL 5O, which was issued on April 15, 2024. The text of GL 5P is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 5P

Authorizing Certain Transactions Related to the Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond on or After November 12, 2024

(a) Except as provided in paragraph (b) of this general license, on or after