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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2024–N–3972]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Hemodialyzer With Expanded Solute Removal Profile

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the hemodialyzer with expanded solute removal profile 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 hemodialyzer with expanded solute removal profile'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 6, 2024. The classification was applicable on August 28, 2020.

FOR FURTHER INFORMATION CONTACT: Jade Noble, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2684, Silver Spring, MD 20993–0002, 240–402–5077, *Jade.Noble@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the hemodialyzer with expanded solute removal profile 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 September 16, 2019, FDA received Baxter Healthcare Corporation's request for De Novo classification of the Theranova Dialyzers (Theranova 400, Theranova 500). 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 August 28, 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 876.5862.[1] We have named the generic type of device hemodialyzer with expanded solute removal profile, and it is identified as a device intended for use as part of an artificial kidney system for the treatment of patient with renal failure by performing such therapies as hemodialysis, hemofiltration, and hemodiafiltration. A hemodialyzer with expanded solute removal profile includes modifications to the semipermeable membrane that allows for increased removal or uremic retention solutes compared with standard high-flux hemodialyzers of the high permeability hemodialysis system classification (§ 876.5860 (21 CFR 876.5860)) including solutes at the upper end of the ''middle'' molecular weight range (0.5 kDa to 60 kDa). This device is intended to be used with the extracorporeal hemodialysis delivery systems, blood tubing sets, blood access devices, and accessories regulated under 21 CFR 876.5820, 876.5860, 876.5540, and/or 876.5600.

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—HEMODIALYZER WITH EXPANDED SOLUTE REMOVAL PROFILE RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation, Pyrogenicity testing, and Non-clinical performance testing.
Infection or pyrogen reaction	Labeling, Pyrogenicity testing, Sterilization validation, Non-clinical performance testing, and Shelf-life testing.
Inadequate or incomplete treatment	Non-clinical performance testing, Labeling, and Shelf-life testing.
Clearance of essential blood substances or medications	Non-clinical performance testing, Clinical performance testing, Labeling, and Shelf-life testing.
Blood loss or blood cell destruction	Non-clinical performance testing, Labeling, and Shelf-life testing.
Blood leak into the dialysis fluid	Non-clinical performance testing, Labeling, and Shelf-life testing.
Air or particle embolism	Non-clinical performance testing, Labeling, and Shelf-life testing.
Fluid imbalance	Non-clinical performance testing and Labeling.
Acid-base imbalance	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. 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.

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 § 876.5862 to read as follows:

§ 876.5862 Hemodialyzer with expanded solute removal profile.

(a) *Identification.* A hemodialyzer with expanded solute removal profile is a device intended for use a part of an artificial kidney system for the treatment of patients with renal failure by performing such therapies as hemodialysis, hemofiltration, and hemodiafiltration. A hemodialyzer with expanded solute removal profile includes modifications to the semipermeable membrane that allows for increased removal of uremic retention solutes compared with standard high-flux hemodialyzers of the high permeability hemodialysis system classification (§ 876.5860), including solutes at the upper end of the ''middle'' molecular weight range (0.5 kDa to 60 kDa). This device is intended to be used with the extracorporeal hemodialysis delivery systems, blood tubing sets, blood access devices, and accessories regulated under §§ 876.5820, 876.5860, 876.5540, and/or 876.5600.

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

(1) Clinical performance testing under anticipated conditions of use must

[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.

evaluate the solute removal profile and document all adverse events.

(2) 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) Ultrafiltration;

(ii) Blood and dialysate pressure drop;

(iii) Clearance rates;

(iv) Sieving coefficients;

(v) Mechanical hemolysis;

(vi) Structural integrity;

(vii) Blood compartment integrity;

(viii) Volume of the blood compartment; and

(ix) Endotoxin retention of the dialyzer membrane.

(3) The tissue-contacting components of the device must be demonstrated to be biocompatible. Biocompatibility evaluation must include a chemical analysis of the dialyzer membrane.

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

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

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

(7) Device labeling must include:

(i) Shelf life;

(ii) Storage conditions;

(iii) Instructions for the preparation of the hemodialyzer, initiation of dialysis, troubleshooting, and discontinuance of dialysis;

(iv) Membrane surface area, priming (blood) volume, maximum transmembrane pressure, maximum blood flow and maximum dialysate rate for each model;

(v) A non-pyrogenic statement;

(vi) A summary of the in vitro performance data, provided in tabular form; and

(vii) A summary of the clinical performance data.

Dated: August 30, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20081 Filed 9–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Parts 548 and 587

Publication of Belarus Sanctions Regulations and Russian Harmful Foreign Activities Sanctions Regulations Web General License 101

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of a 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 Belarus Sanctions Regulations and Russian Harmful Foreign Activities Sanctions Regulations: GL 101 which was previously made available on OFAC's website.

DATES: GL 101 was issued on August 9, 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 9, 2024, OFAC issued GL 101 to authorize certain transactions otherwise prohibited by the Belarus Sanctions Regulations, 31 CFR part 548, and the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587. The GL was made available on OFAC's website (*https://ofac.treasury.gov*) when it was issued and has an expiration date of September 10, 2024. The text of this GLs is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Belarus Sanctions Regulations

31 CFR Part 548

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 101

Authorizing Civil Aviation Safety and Wind Down Transactions Involving Certain Entities Blocked on August 9, 2024

(a) Except as provided in paragraph (c) of this general license, all transactions prohibited by the Belarus Sanctions Regulations, 31 CFR part 548 (BSR), and Executive Order (E.O.) 14024, that are ordinarily incident and necessary to the provision, exportation, or reexportation of goods, technology, or services to ensure the safety of civil aviation involving one or more of the following blocked entities (collectively, the ''Blocked Entities'') are authorized through 12:01 a.m. eastern daylight time, September 10, 2024, provided that the goods, technology, or services that are provided, exported, or reexported are for use on aircraft operated solely for civil aviation purposes:

(1) Aviakompaniya Belkanto LLC;

(2) Aviakompaniya Rada LLC;

(3) UE RubiStar; or

(4) Any entity in which one or more of the above persons owns, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest.

(b) Except as provided in paragraph (c) of this general license, all transactions prohibited by the BSR or E.O. 14024 that are ordinarily incident and necessary to the wind down of any transaction involving any of the Blocked Entities are authorized through 12:01 a.m. eastern daylight time, September 10, 2024, provided that any payment to a Blocked Entity is made into a blocked account in accordance with the BSR and the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR).

(c) This general license does not authorize:

(1) Any transactions otherwise prohibited by the BSR or the RuHSR, including transactions involving any person blocked pursuant to the BSR or the RuHSR other than the Blocked Entities, unless separately authorized;

(2) Any transactions prohibited by Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;* or

(3) Any transactions prohibited by Directive 4 under E.O. 14024, *Prohibitions Related to Transactions Involving the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, and the Ministry of Finance of the Russian Federation.*

Note to General License 101. Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies, including export, reexport, and transfer (in-country) licensing requirements maintained by the Department of Commerce's Bureau of