(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0184 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k) of this AD and email to: *ANE-AD-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7241; email: *Sungmo.D.Cho@faa.gov*.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) European Union Aviation Safety Agency AD 2022–0184, dated September 2, 2022.

(ii) [Reserved]

(3) For more information about EASA AD 2022–0184, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on December 14, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–28221 Filed 12–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2022–N–3185]

Medical Devices; Cardiovascular Devices; Classification of the Interventional Cardiovascular Implant Simulation Software Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency or we) is classifying the interventional cardiovascular implant simulation software 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 interventional cardiovascular implant simulation software 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 28, 2022. The classification was applicable on September 8, 2021.

FOR FURTHER INFORMATION CONTACT: Judy Ji, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2543, Silver Spring, MD, 20993–0002, 301–796–6949, *Judy.Ji@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the interventional cardiovascular implant simulation software 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, 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).

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 May 7, 2020, FDA received FEops NV's request for De Novo classification of the FEops HEARTguide. 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 September 8, 2021, 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 870.1405.[1] We have named the generic type of device interventional cardiovascular implant simulation software device, and it is identified as a prescription device that provides a computer simulation of an interventional cardiovascular implant device inside a patient's cardiovascular anatomy. It performs computational modeling to predict the interaction of the interventional cardiovascular implant device with the patient-specific anatomical environment.

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—INTERVENTIONAL CARDIOVASCULAR IMPLANT SIMULATION SOFTWARE DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Inaccurate simulation results leading to selection of suboptimal treatment plan, leading to prolonged procedure time and/or patient injury.	Software verification, validation, and hazard analysis; Computational modeling verification and validation; Performance validation with clinical data; Labeling; and Human factors testing.
Delayed delivery of results due to software failure or use error, leading to delay of treatment.	Software verification, validation, and hazard analysis; Human factors testing; and Labeling.
Failure to properly interpret device results leading to selection of suboptimal treatment plan, leading to prolonged procedure time and/or patient injury.	Human factors 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.

At the time of classification, interventional cardiovascular implant simulation software device is 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 parts 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:

PART 870—CARDIOVASCULAR DEVICES

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

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

■ 2. Add § 870.1405 to subpart B to read as follows:

§ 870.1405 Interventional cardiovascular implant simulation software device.

(a) *Identification.* An interventional cardiovascular implant simulation software device is a prescription device that provides a computer simulation of an interventional cardiovascular implant device inside a patient's cardiovascular anatomy. It performs computational modeling to predict the interaction of the interventional cardiovascular implant device with the patient-specific anatomical environment.

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

(1) Software verification, validation, and hazard analysis, with identification of appropriate mitigations, must be performed, including a full verification and validation of the software according to the predefined software specifications.

(2) Computational modeling verification and validation activities must be performed to establish the predictive capability of the device for its indications for use.

(3) Performance validation testing must be provided to demonstrate the accuracy and clinical relevance of the modeling methods for the intended implantation simulations, including the following:

(i) Computational modeling results must be compared to clinical data supporting the indications for use to demonstrate accuracy and clinical meaningfulness of the simulations;

(ii) Agreement between computational modeling results and clinical data must be assessed and demonstrated across the full intended operating range (*e.g.,* full range of patient population, implant device sizes and patient anatomic morphologies). Any selection criteria or limitations of the samples must be described and justified;

(iii) Endpoints (*e.g.,* performance goals) and sample sizes established must be justified as to how they were determined and why they are clinically meaningful; and

(iv) Validation must be performed and controls implemented to characterize and ensure consistency (*i.e.,* repeatability and reproducibility) of modeling outputs:

(A) Testing must be performed using multiple qualified operators and using the procedure that will be implemented under anticipated conditions of use; and

(B) The factors (*e.g.,* medical imaging dataset, operator) must be identified regarding which were held constant and which were varied during the evaluation, and a description must be provided for the computations and statistical analyses used to evaluate the data.

(4) Human factors evaluation must be performed to evaluate the ability of the user interface and labeling to allow for intended users to correctly use the device and interpret the provided information.

(5) Device labeling must be provided that describes the following:

(i) Warnings that identify anatomy and image acquisition factors that may impact simulation results and provide cautionary guidance for interpretation of the provided simulation results;

(ii) Device simulation inputs and outputs, and key assumptions made in the simulation and determination of simulated outputs; and

(iii) The computational modeling performance of the device for presented simulation outputs, and the supporting evidence for this performance.

Dated: December 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28173 Filed 12–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 587

Publication of Russian Harmful Foreign Activities Sanctions Regulations Web General Licenses 8D and 40C

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of Web General Licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing two general licenses (GLs) issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations: GLs 8D and 40C, which were previously made available on OFAC's website.

DATES: GL 8D was issued on November 10, 2022. 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 Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

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

Background

On November 10, 2022, OFAC issued GL 8D to authorize certain transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR). On November 14, 2022, OFAC issued GL 40C to authorize certain transactions otherwise prohibited by the RuHSR. At the time of issuance, OFAC made GLs 8D and 40C available on its website (*www.treas.gov/ofac*). The text of these GLs is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations; 31 CFR Part 587

GENERAL LICENSE NO. 8D

Authorizing Transactions Related to Energy

(a) Except as provided in paragraph (c) of this general license, all transactions prohibited by Executive Order (E.O.) 14024 involving one or more of the following entities that are related to energy are authorized, through 12:01 a.m. eastern daylight time, May 15, 2023.

(1) State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank;

(2) Public Joint Stock Company Bank Financial Corporation Otkritie;

(3) Sovcombank Open Joint Stock Company;

(4) Public Joint Stock Company Sberbank of Russia;

(5) VTB Bank Public Joint Stock Company;

(6) Joint Stock Company Alfa-Bank;

(7) Any entity in which one or more of the above persons own, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest; or

(8) the Central Bank of the Russian Federation.

(b) For the purposes of this general license, the term ''related to energy'' means the extraction, production, refinement, liquefaction, gasification, regasification, conversion, enrichment, fabrication, transport, or purchase of petroleum, including crude oil, lease condensates, unfinished oils, natural gas liquids, petroleum products, natural gas, or other products capable of producing energy, such as coal, wood, or agricultural products used to manufacture biofuels, or uranium in any form, as well as the development, production, generation, transmission, or exchange of power, through any means, including nuclear, thermal, and renewable energy sources.

(c) This general license does not authorize: