DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2026–N–9906]

Medical Devices; Cardiovascular Devices; Classification of the Extravascular Support for an Arteriovenous Fistula for Vascular Access

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the extravascular support for an arteriovenous fistula for vascular access 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 classification of the extravascular support for an arteriovenous fistula for vascular access. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective September 10, 2026. The classification was applicable on September 26, 2023.

FOR FURTHER INFORMATION CONTACT: Nicole Schiavone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2570, Silver Spring, MD 20993–0002, 240–402–4053, *Nicole.Schiavone@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the extravascular support for an arteriovenous fistula for vascular access into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens 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 into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (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 (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 classification 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 premarket notification (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.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. 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 29, 2022, FDA received Laminate Medical Technologies Ltd.'s request for De Novo classification of the VasQ 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 the safety and effectiveness of the device, 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 section 513(a)(1)(B) of the FD&C Act). 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 26, 2023, 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 870.4600.[1] We have named the generic type of device ''extravascular support for an arteriovenous fistula for

[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.

vascular access,'' and it is identified as a permanent implant which is surgically placed outside and/or around an artery and/or vein to provide external support to arteriovenous fistulas created for vascular access by means of vascular surgery.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR EXTRAVASCULAR SUPPORTS FOR AN ARTERIOVENOUS FISTULA FOR VASCULAR ACCESS

Identified risks to health	Mitigation measures
Vascular or tissue injury or bleeding	Clinical performance testing; Animal performance testing; Non-clinical performance testing; and Labeling.
Adverse effect of hemodynamics of the arteriovenous fistula	Clinical performance testing; and Animal performance testing.
Failure to support a durable fistula that is usable for vascular access	Clinical performance testing; and Animal performance testing.
Use of the device adversely impacts future vascular access sites	Clinical performance testing; and Labeling.
Mechanical device failure/malfunction leading to injury or fistula failure	Clinical performance testing; Non-clinical performance testing; and Labeling.
Improper size selection	Labeling.
Improper device placement	Labeling.
Imaging incompatibility	Non-clinical performance testing; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Sterilization validation; Shelf-life 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 the safety and effectiveness of the device. 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 final order. FDA supports the principles of the ''3Rs,'' to replace, reduce, and/or refine animal use in testing when feasible. 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 whether such an alternative method could be assessed for equivalency to an animal test method.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for extravascular supports for an arteriovenous fistula for vascular access. This device is therefore 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 normally 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 management 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 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:

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

■ 2. Add § 870.4600 to subpart E to read as follows:

§ 870.4600 Extravascular support for an arteriovenous fistula for vascular access.

(a) *Identification.* This device is a permanent implant which is surgically placed outside and/or around an artery and/or vein to provide external support to arteriovenous fistulas created for vascular access by means of vascular surgery.

(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. Testing must evaluate:

(i) The ability to safely implant the device;

(ii) The ability of the arteriovenous fistula supported by the device to attain a blood flow rate and diameter suitable for hemodialysis;

(iii) The ability of the fistula to be used for vascular access;

(iv) The primary, assisted primary, and secondary patency of the fistula;

(v) The rates and types of device integrity events and any associated clinical sequelae;

(vi) The rates and types of all adverse events; and

(vii) The rates and outcomes of reinterventions.

(2) If FDA determines that premarket clinical information is insufficient to evaluate long-term safety and effectiveness of the product, postmarket data must be collected through an adequately designed and powered postmarket study to assess the following:

(i) The functionality and patency of the fistula through a clinically meaningful timeframe;

(ii) The rates and types of access-related, reintervention-related, and cannulation-related adverse events; and

(iii) The reasons for, rates, types, and outcomes of reinterventions.

(3) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be assessed:

(i) Implantation of the device;

(ii) Patency of the fistula; and

(iii) Gross pathology and histopathology assessing vascular injury and downstream embolization.

(4) 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) Resistance to kinking;

(ii) Resistance to crush and local compression;

(iii) Tensile strength of joints and components;

(iv) Device integrity;

(v) Corrosion resistance; and

(vi) Characterization and verification of all dimensions.

(5) Non-clinical testing must evaluate the compatibility of the device in a magnetic resonance (MR) environment.

(6) All patient-contacting components of the device must be demonstrated to be biocompatible.

(7) Performance data must demonstrate sterility of the device components intended to be provided sterile.

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

(9) Labeling for the device must include:

(i) Specific instructions regarding device size selection and device placement;

(ii) Expertise needed for safe use of the device;

(iii) A detailed summary of the clinical testing conducted and the patient population studied, including information on effectiveness and device- and procedure-related complications;

(iv) A detailed summary of the device technical parameters;

(v) A shelf life and storage conditions; and

(vi) MR information.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2026–N–9910]

Medical Devices; Cardiovascular Devices; Classification of the Temperature Regulation Device for Esophageal Protection During Cardiac Ablation Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the temperature regulation device for esophageal protection during cardiac ablation procedures 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 classification of the temperature regulation device for esophageal protection during cardiac ablation procedures. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective September 10, 2026. The classification was applicable on September 13, 2023.

FOR FURTHER INFORMATION CONTACT: David Hazlewood, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2227, Silver Spring, MD 20993–0002, 240–402–3641, *David.Hazlewood@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the temperature regulation device for esophageal protection during cardiac ablation procedures into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens 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 into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (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 (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 classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

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