TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR ANTI-TUMOR NECROSIS FACTOR ALPHA MONOCLONAL ANTIBODY TEST SYSTEMS FOR INFLAMMATORY BOWEL DISEASE

Identified risks to health	Mitigation measures
Incorrect test results	Certain design verification and validation activities and documentation, including certain studies. Certain labeling information, including certain limiting statements.
Incorrect interpretation of test results.	Certain design verification and validation activities and documentation, including certain studies. Certain labeling information, including certain limiting statements.

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.

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 anti-tumor necrosis factor alpha monoclonal antibody test systems for inflammatory bowel disease. 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 parts 801 and 809 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

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

■ 2. Add § 862.3115 to subpart D to read as follows:

§ 862.3115 Anti-tumor necrosis factor alpha monoclonal antibody test system for inflammatory bowel disease.

(a) *Identification.* An anti-tumor necrosis factor alpha monoclonal antibody test system is an in vitro diagnostic device intended for the measurement of an anti-tumor necrosis factor alpha monoclonal antibody as an aid in the management of patients with Crohn's disease or ulcerative colitis.

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

(1) Design verification and validation must include the following:

(i) Detailed documentation of studies that demonstrate the analytical performance of the device for its intended use, including for each analyte and device output. These studies must demonstrate analytical performance for each monoclonal antibody analyte and device output that is adequate to support all intended clinical uses, including all of its indications for use, and testing environments. These studies must include precision, reproducibility, linearity, accuracy, high dose hook effect, sample stability, detection limits (including limit of blank, limit of detection, and limit of quantification) and analytical specificity studies, or alternative approaches determined to be appropriate by FDA.

(ii) Detailed documentation of data that is adequate to support the accuracy of the device and/or device performance for all intended clinical uses, including all of its indications for use, as determined to be appropriate by FDA.

(iii) Detailed documentation demonstrating traceability of the device to an internationally recognized reference material, as determined to be appropriate by FDA.

(2) The labeling required under § 809.10(b) of this chapter must include limiting statements including the following:

(i) The device should not be used for conditions other than Crohn's disease or ulcerative colitis.

(ii) The test result is intended as an aid in the management of the patient, and not to be used to replace clinical judgment.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18430 Filed 9–9–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2026–N–9905]

Medical Devices; Cardiovascular Devices; Classification of the Mechanical Deviation 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 mechanical deviation 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 mechanical deviation 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 6, 2023.

FOR FURTHER INFORMATION CONTACT: Aneesh Deoras, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5540, Silver Spring, MD 20993–0002, 240–402–4363, *Aneesh.Deoras@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the mechanical deviation 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.

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 January 24, 2023, FDA received S4 Medical Corp.'s request for De Novo classification of the esolution Esophageal Retractor. 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 6, 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 870.5710.[1] We have named the generic type of device ''mechanical deviation device for esophageal protection during cardiac ablation procedures,'' and it is identified as a device that is placed in the lumen of the esophagus to reduce the likelihood of esophageal injury or a specific adverse event during cardiac ablation procedures. The device uses mechanical means to deviate the esophagus away from the source of ablation energy.

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

[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.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR MECHANICAL DEVIATION DEVICES FOR ESOPHAGEAL PROTECTION DURING CARDIAC ABLATION PROCEDURES

Identified risks to health	Mitigation measures
Failure to protect the esophagus during ablation leading to esophageal perforating complications.	Clinical performance testing; animal performance testing; non-clinical performance testing; and labeling.
Device malfunction leading to esophageal injury	Non-clinical performance testing; and shelf life and packaging testing.
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Sterilization validation; shelf life and packaging testing; and labeling.
Mechanical injury to esophageal or oral structures	Clinical performance testing; animal 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 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 mechanical deviation devices for esophageal protection during cardiac ablation procedures. 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 § 870.5710 to subpart F to read as follows:

§ 870.5710 Mechanical deviation device for esophageal protection during cardiac ablation procedures.

(a) *Identification.* This device is placed in the lumen of the esophagus to reduce the likelihood of esophageal injury or a specific adverse event during cardiac ablation procedures. The device uses mechanical means to deviate the esophagus away from the source of ablation energy.

(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 and include the following:

(i) Evaluation of reduction of the incidence of esophageal injury during cardiac ablation procedures; and

(ii) Evaluation of any esophageal or oral injury from use of the device.

(2) Animal performance testing must demonstrate that the device performs as intended under the anticipated conditions of use and include the following:

(i) Evaluation of the device's capability to adequately deviate the esophagus, including its trailing edge, away from the source of ablation energy; and

(ii) Evaluation of any esophageal injury from use of the device.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Mechanical integrity testing using clinically relevant forces; and

(ii) Compatibility testing with accessory devices.

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

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

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

(7) Labeling must include the following:

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

(ii) A shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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