4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA-2025-N-4645]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Anchored Esophageal Sheath

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the anchored esophageal sheath 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 classification of the anchored esophageal sheath. 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, in part by reducing regulatory burdens.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Anthony Lee, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4549, Silver Spring, MD 20993-0002, 240-402-5935, Anthony.Lee1@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the anchored esophageal sheath as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness for its intended use. In addition, we believe this action will enhance patients'

access to beneficial innovation, in part by reducing regulatory burdens by placing the device into the appropriate device class based on risk and the regulatory controls sufficient to provide reasonable assurance of safety and effectiveness.

FDA may classify a device through an accessory classification request under section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(6)), established by section 707 of the FDA Reauthorization Act of 2017 (Pub. L. 115-52). The provision allows manufacturers or importers to request classification of an accessory distinct from another device upon written request. The classification is based on the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request appropriate classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the *Federal Register* within 30 days of announcing the classification.

Alternatively, under section 513(f)(6)(C) of the FD&C Act, a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or

510(k). Upon granting, FDA will publish a notice in the *Federal Register* within 30 days of announcing the classification.

II. Accessory Classification

On July 9, 2018, FDA received BAROnova, Inc.'s request for accessory classification of the BAROnova Access Sheath. 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 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 April 16, 2019, 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 876.1510.[1] We have named the generic type of device "anchored esophageal sheath," and it is identified as a device used to provide an endoluminal pathway to facilitate insertion of an endoscope or other compatible device into the upper gastrointestinal tract. A distal anchor assists in keeping the sheath in place to facilitate positioning of the endoscope or other compatible device.

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.

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[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.--Anchored Esophageal Sheath Risks and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Mechanical injury to esophagus and/or gastroesophageal junction (GEJ) related to: • Insertion/removal of anchored esophageal sheath • Insertion/removal of endoscope or other compatible device through anchored esophageal sheath • Actuation of anchoring component into anchored configuration within esophagus • Retraction of anchoring component against GEJ	Non-clinical performance testing; Simulated use testing; 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 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 final order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act (21 U.S.C. 360(k)).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. At a future date, we may publish a separate notice in *the Federal Register* announcing our intent to exempt this device type.

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 the guidance document "Medical Device Accessories–Describing Accessories and Classification Pathways" have been approved under OMB control number 0910-0823; the collections of information in part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910-0231; the collections of information in part 820 regarding quality system regulation have been approved under OMB control number 0910-0073; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120; and the collections of information in 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 § 876.1510 to subpart B to read as follows:

§ 876.1510 Anchored esophageal sheath.

(a) *Identification*. An anchored esophageal sheath is a device used to provide an endoluminal pathway to facilitate insertion of an endoscope or other compatible device into the

upper gastrointestinal tract. A distal anchor assists in keeping the sheath in place to facilitate positioning of the endoscope or other compatible device.

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

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

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Testing must verify all dimensions;

(ii) Testing must demonstrate that insertion and removal of any device from the anchored esophageal sheath does not damage the shaft wall or exert force that would cause tissue injury;

(iii) Testing must demonstrate that the anchoring component can be reliably actuated;

(iv) Testing must demonstrate compatibility with any other device that the anchored esophageal sheath is intended to be used with; and

(v) Testing must demonstrate device integrity and functionality in simulated gastric conditions under clinically anticipated forces.

(3) Simulated use testing using an anatomically accurate gastrointestinal model must demonstrate that:

(i) The device can be inserted and removed safely;

(ii) The device remains anchored in place;

(iii) The device can be safely withdrawn after releasing the anchor; and

(iv) The device location and anchoring status can be observed by the intended user.

(4) Performance data must demonstrate continued device functionality over the identified shelf life.

(5) Labeling must include:

(i) Information as to whether the device can be used for foreign body removal or with instruments alongside the endoscope;

(ii) Steps needed to prevent injury to the esophagus or gastroesophageal junction (GEJ) during placement, anchoring, and use of the device;

(iii) Any visualization steps required to confirm the device's placement prior to and after actuating the anchoring component at the GEJ;

(iv) A precaution to avoid excessive force during insertion;

(v) Identification of any endoscopes or other devices that have been validated for use with the anchored esophageal sheath; and

(vi) An expiration date or shelf life.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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