compatibility of the device in the intended use environment.

(7) Methods and instructions for reprocessing reusable components must be validated.

(8) Labeling must include:

(i) Device technical parameters, including a description of the accuracy of the device;

(ii) Information regarding endoscope compatibility;

(iii) Warning for light hazards and protection for patient and operator; and

(iv) Validated reprocessing instructions.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12444 Filed 6–18–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2026–N–5149]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Endoscopic Traction Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the endoscopic traction 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 classification of the endoscopic traction device. We are taking this action because we have determined that classifying the device into class II 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 June 22, 2026. The classification was applicable on June 13, 2022.

FOR FURTHER INFORMATION CONTACT: Sivakami Venkatachalam, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2676, Silver Spring, MD 20993–0002, 301–796–9103, *Sivakami.Venkatachalam@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the endoscopic traction device into class II (special controls), which we have determined will provide a reasonable assurance of 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 14, 2022, FDA received Covidien LLC's request for De Novo classification of the ProdiGI 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 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 June 13, 2022, 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 876.4410.[1] We have named the generic type of device ''endoscopic traction device,'' and it is identified as a prescription device that is endoscopically applied to retract tissue in the gastrointestinal tract during dissection procedures to increase visualization of the dissection plane and assist in tissue resection, exposure, and removal.

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 ENDOSCOPIC TRACTION DEVICES

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Tissue trauma including bleeding, perforation, or laceration due to use error or improper device use.	In vivo performance testing; Non-clinical performance testing; Usability assessment; and Labeling.
Infection	Sterilization validation; Shelf life testing; and Labeling.
Device failure/malfunction leading to patient injury	Non-clinical performance testing.
Increased procedure time and sedation time due to time needed to deploy device.	In vivo performance testing; and Usability assessment.

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 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 if such an alternative method could be assessed for equivalency to an animal test method.

At the time of classification, endoscopic traction devices are 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.

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 endoscopic traction devices. 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 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 § 876.4410 to subpart E to read as follows:

§ 876.4410 Endoscopic traction device.

(a) *Identification.* An endoscopic traction device is a prescription device that is endoscopically applied to retract tissue in the gastrointestinal tract during dissection procedures to increase visualization of the dissection plane and assist in tissue resection, exposure, and removal.

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

(1) In vivo performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate:

[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.

(i) Perforation, bleeding, and mucosal injury;

(ii) Ease of insertion and removal of the device;

(iii) Visualization during the procedure; and

(iv) Ease of procedure as reported by the intended user.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:

(i) Device deployment and detachment;

(ii) Ability to retract tissue;

(iii) Tensile strength;

(iv) Potential for laceration caused by the device or procedure using the device;

(v) Dimensional verification; and

(vi) For devices that contain a magnet, magnet strength verification and safety assessment.

(3) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.

(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 biocompatible.

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

(7) Labeling must include:

(i) The recommended training for safe use of the device;

(ii) Anatomical locations and lesion sizes that have been demonstrated to be safe to use with the device; and

(iii) A shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12445 Filed 6–18–26; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[SATS No. WV–118–FOR; OSM–2011–0009; and WV–117–FOR; OSM–2011–0006; S1D1S SS08011000 SX064A000 267S180110; S2D2S SS08011000 SX064A000 26XS501520]

West Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment with two provisions receiving qualified approval.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving two amendments to the West Virginia regulatory program (the West Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). West Virginia proposed revisions to the West Virginia Surface Coal Mining and Reclamation Act (WVSCMRA), codified at Title 22, Article 3, of the West Virginia Code (W. Va. Code), along with revisions to its administrative regulations promulgated in the West Virginia Code of State Rules (CSR) that relate to electronic permit filing, pre-subsidence surveys, and issuance of show cause orders, certain fees for surface mining permits and related authorizations, and other miscellaneous topics. We tentatively approved the provisions relating to permitting fees through an interim rule we promulgated on June 29, 2011, which became effective on July 14, 2011. With this rule, our approval of those provisions is now final.

DATES: This rule is effective July 22, 2026.

FOR FURTHER INFORMATION CONTACT: Mr. Justin Adams, Director, Charleston Field Office, Telephone: (304)-977–7450. Email: *osm-chfo@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the West Virginia Program

Subject to OSM's oversight, section 503(a) of SMCRA permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the West Virginia program on January 21, 1981. You can find additional background information on the West Virginia program, including the Secretary's findings, the disposition of comments, and conditions of approval of the West Virginia program in the January 21, 1981, **Federal Register** (46 FR 5915). You can also find later actions concerning West Virginia's program and program amendments at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Submission of the Amendment

In 2011, the West Virginia Legislature passed revisions to WVSCMRA and the state regulations through Senate Bill 121 (SB 121) (March 11, 2011) and House Bill 2955 (HB 2955) (approved March 18, 2011). *See* 2011 W. Va. Acts Chs. 109 and 166. SB 121 codified several revisions to the CSR, establishing an incremental bonding rate that we approved on an interim basis in 2011, *see* 76 FR 37996 (June 29, 2011), revising provisions to accommodate electronic permit filing, establishing trust funds and annuities as an alternative to traditional performance bond for long-term water treatment, and making other miscellaneous revisions discussed below. HB 2955 established or revised several permit-related fees that we approved in our 2011 interim rule.

A. WV–117–FOR

By letter dated April 21, 2011 (Administrative Record Number WV–1557), the West Virginia Department of Environmental Protection (WVDEP) submitted to us a program amendment, which we docketed at SATS No. WV–117–FOR, that included the permit fee revisions from HB 2955, along with the revisions to the CSR from SB 121 that established the incremental bonding rate. HB 2955 increased the filing fee for the State's surface mining permit to $3,500, increased the permit renewal fee to $3,000, and established various fees for other permit-related actions like significant permit revisions and notices of intent to prospect. We approved the increase in permit fees on an interim basis. In our interim approval on June 29, 2011, we requested public comments and provided an opportunity for a public hearing on the permit fees and incremental bonding rate revisions (Administrative Record No. 1560).[1] West Virginia subsequently submitted, and we approved, significant revisions to its incremental bonding provisions in a program amendment, which we docketed at SATS No. WV–126–FOR. WV–129–FOR rendered the incremental bonding revision from WV–117–FOR moot. *See* 89 FR 19262, 19266 (Mar. 18, 2024). Therefore, we will not further

[1] In our June 29, 2011, notice (76 FR 37996), we erroneously omitted the rule's effective date. We published a correction on July 14, 2011 (76 FR 41411), stating that the effective date was July 14, 2011.