



June 13, 2022

Covidien LLC
Liron Bar Yaakov
Sr. Manager of Regulatory Affairs
3062 Bunker Hill Lane
Santa Clara, CA 95054

Re: DEN220006
Trade/Device Name: ProdiGI
Regulation Number: 21 CFR 876.4410
Regulation Name: Endoscopic traction device
Regulatory Class: Class II
Product Code: QSW
Dated: January 13, 2022
Received: January 14, 2022

Dear Liron Bar Yaakov:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ProdiGI, a prescription device under 21 CFR Part 801.109 with the following indications for use:

ProdiGI Traction Wire:

The Medtronic ProdiGI Traction Wire is indicated to grasp tissue within the esophagus, stomach, and colon of adults during an Endoscopic Submucosal Dissection (ESD) procedure.

ProdiGI Traction Magnet:

The Medtronic ProdiGI Traction Magnet is indicated to grasp tissue within the stomach and colon of adults during an Endoscopic Submucosal Dissection (ESD) procedure.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ProdiGI, and substantially equivalent devices of this generic type, into Class II under the generic name endoscopic traction device.

FDA identifies this generic type of device as:

Endoscopic traction device. 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On January 14, 2022, FDA received your De Novo requesting classification of the ProdiGI. The request was submitted under section 513(f)(2) of the FD&C Act. To classify the ProdiGI into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the ProdiGI can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risk to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Tissue trauma including bleeding, perforation, or laceration due to use error or improper device use	<i>In vivo</i> performance testing Non-clinical performance testing Usability assessment Labeling
Infection	Sterilization validation Shelf life testing 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	<i>In vivo</i> performance testing Usability assessment

In combination with the general controls of the FD&C Act, the endoscopic traction device is subject to the following special controls:

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

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

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) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the endoscopic traction device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Sivakami Venkatachalam at 301-796-9103.

Sincerely,

Courtney H. Lias, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health