DE NOVO CLASSIFICATION REQUEST FOR PRODIGI

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 876.4410

CLASSIFICATION: Class II

PRODUCT CODE: QSW

BACKGROUND

DEVICE NAME: ProdiGI

SUBMISSION NUMBER: DEN220006

DATE DE NOVO RECEIVED: January 14, 2022

SPONSOR INFORMATION:

Covidien LLC
3062 Bunker Hill Lane
Santa Clara, California 95054

INDICATIONS FOR USE

The ProdiGI is indicated as follows:

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.

LIMITATIONS

The sale, distribution, and use of the ProdiGI are restricted to prescription use in accordance with 21 CFR 801.109.

The traction device should only be used by a physician trained in therapeutic endoscopy, including training in submucosal dissection.

No portion of the device is intended to be an implant. The entire device must be removed at the end of the procedure.

Device contains nickel in the form of nitinol and stainless steel. Caution should be taken for patients with potential nickel allergies.

The magnet of the device may cause interference with metallic (e.g., stent) or magnetic implants. Exercise care when passing the device near such implants and consult the implant's manufacturer's instruction for any safety concerns.

The Medtronic ProdiGI Traction Wire Device and Traction Magnet Device is contraindicated for use in patients with known or suspected varices or other structures at risk of significant bleeding at the targeted deployment location.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The ProdiGI Traction System includes the Traction Wire and Traction Magnet devices. The Traction Wire and Traction Magnet are not intended to be used together. Both devices are used in adults only and are used to provide improved visualization of the submucosal space during an endoscopic submucosal dissection (ESD) procedure.

ProdiGI Traction Wire Device

The Traction Wire consists of two graspers: a primary tissue grasper with traction wire attached (ERD-TW20 and ERD-TW35), and a secondary tissue grasper (ERD-TWSG) without a wire. The secondary tissue grasper is used to secure the distal end of the traction wire. The traction wire is a nitinol shape-memory loop (2.0 cm or 3.5 cm in length) that provides tension to the attached tissue after deployment. The nitinol wire is attached to the grasper with a stainless-steel crimp. No functional or mechanical differences are present in the 2.0 cm and 3.5 cm device lengths. Wire length size differences allow physicians to select a Traction Wire best suited for the location and size of the target treatment site.

Figure 1. ProdiGI Traction Wire Device consists of two graspers, the primary grasper with nitinol wire attached and secondary grasper with no wire attached

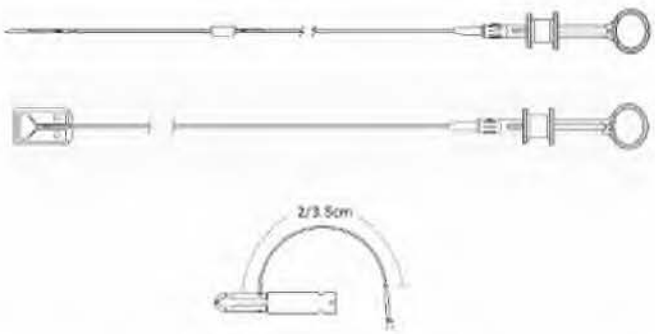

Figure 2. Diagram of traction wire device deployment device (top) and nitinol wire attached to grasper arm (bottom)

The primary traction wire grasper has a long shaft (b)(4) and is designed to be inserted and passed through the working channel of an endoscope. It is compatible with endoscopes with a maximum working length of 1700 mm and working channels 2.8 mm or greater. After passing through the endoscope, the device is directed to the targeted gastrointestinal tissue by manipulation of the endoscope and grasper. Upon obtaining proper positioning, the traction wire is deployed onto the targeted tissue through the attached handle. The graspers themselves are constructed of stainless-steel and open to a minimum distance of (b)(4)

The secondary tissue grasper (ERD-TWSG) is also designed to be inserted through the working channel of an endoscope. After passing through the endoscope, the device is used to grasp and secure the free end of the wire to the targeted gastrointestinal tissue. Upon obtaining proper positioning, the secondary grasper is deployed onto the tissue through the attached handle. An additional secondary tissue grasper (ERD-TWSG) can be used if desired to adjust secondary grasper position mid procedure. The secondary grasper has a (b)(4) shaft with distal end graspers controlled at the proximal handle. The graspers are constructed of stainless steel and open to a minimum distance of (b)(4)

Once the Traction Wire is deployed and positioned, it facilitates cutting and improves visualization of the dissection plane by causing the lesion to progressively roll back on itself

during dissection, as the nitinol wire bends back into its pre-shaped curved configuration. After the target lesion has been successfully excised from the treatment site, the tissue and traction device are removed from the patient.

To remove the excised lesion and graspers from the patient, the secondary grasper is removed from the tissue using endoscopic tools such as grasping forceps. Secondary graspers (those placed outside resection area) have been designed to be atraumatic allowing for removal without adding significant tissue trauma to the procedure. Traction Wire Secondary Graspers are rounded to allow for sliding over tissue.

ProdiGI Traction Magnet Device

The traction magnet (ERD-TMST and ERD-TMLG) consists of two identical tissue graspers with a permanent neodymium magnet ((b)(4) attached to the grasper via a (b)(4) suture. The sutured magnet provides tension to the attached tissue after deployment. No functional or mechanical differences are present in the (b)(4) (TMLG) and (b)(4) (b)(4) (TMST) suture lengths. Suture length size differences allow physicians to select a traction magnet best suited for the location and size of the target treatment site.

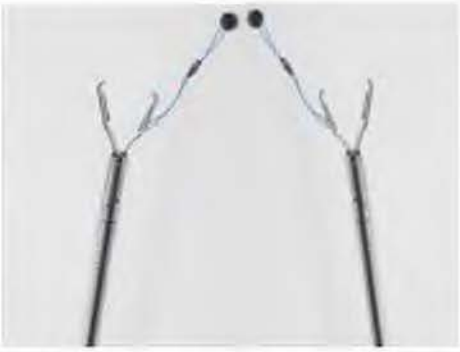

Figure 3. ProdiGI Tration Magnet device consists of two graspers, both with a suture and magnet attached

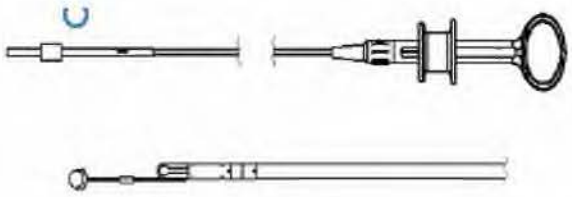

Figure 4. Diagram of traction magnet device deployment device (top) and suture with magnet attached to grasper arm (bottom)

The grasper is designed to be inserted and passed through the working channel of an endoscope. It is compatible with endoscopes with a maximum working length of 1700 mm and working channels 2.8 mm or greater. After passing through the endoscope, the device is directed to the

targeted gastrointestinal tissue by manipulation of the endoscope and grasper. Upon obtaining proper positioning, the traction magnet is deployed onto the targeted tissue through the attached handle.

After passing the second grasper through the endoscope, the magnet of the second device is joined to the magnet of the first device on the lesion and positioned to the targeted gastrointestinal tissue opposite of the lesion. Upon obtaining proper positioning, the second grasper is deployed onto the tissue through the attached handle. Additional devices can be used if desired to adjust traction mid procedure.

The amount of traction provided during the procedure is controlled by inflating/deflating the organ in which the ESD procedure is being performed. The device on the opposing tissue from the lesion can be removed from the tissue with endoscopic tools such as grasping forceps.

SUMMARY OF NONCLINICAL/BENCH STUDIES

Non-clinical/bench studies conducted on the ProdiGI device demonstrate a reasonable assurance of safety and effectives of the device and are summarized below:

BIOCOMPATIBILITY/MATERIALS

The patient contacting components of the ProdiGI device include both the Traction Wire and the Traction Magnet devices. These devices were evaluated with respect to their intended use per ISO 10993-1:2003, Biological evaluation of medical devices and FDA Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.'" Testing was performed on final finished devices. The following tests were performed on the ProdiGI devices:

1. Cytotoxicity
2. Sensitization
3. Irritation or Intracutaneous Reactivity
4. Material-Mediated Pyrogenicity
5. Acute Systemic Toxicity

The results supported the biocompatibility of the ProdiGI device.

SHELF LIFE/STERILITY

The ProdiGI device is a sterile, single use system. Sterilization was evaluated for conformance to ANSI/AAMI/ISO 11135:2014 "Sterilization of health care products - Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices," to ensure a sterility assurance level of 10^{-6} before the device is marketed.

Accelerated aging to support a 1.5-year shelf life was performed for the EO sterilized ProdiGI devices per ASTM F1980-16, Standard Guidance for Accelerated Aging of Sterile Barrier Systems and Medical Devices. The shelf life was verified by demonstrating packaging integrity through gross leak detection testing and pouch seal strength testing on the stored devices.

PERFORMANCE TESTING - BENCH

Non-clinical performance tests were conducted to demonstrate mechanical integrity and functionality of the ProdiGI devices. The table below summarizes each of these bench tests, which includes appropriate acceptance criteria for the intended use of the device.

Bench testing was done to evaluate the mechanical performance and durability of the device. The traction wire comes in two models, ERD-TW20 and ERD-TW35. Both traction wires are also used with a secondary grasper ERD-TWSG. All three of these models are similar in all aspects of their materials and construction, except for the length of nitinol wire attached. The longest nitinol wire device, ERD-TW35, was used as a representative model for testing. Likewise, the traction magnet comes in two sizes, ERD-TWSM and ERD-TWLG. Both models are identical in construction and materials, except for the length of the attached suture. Both models were used for testing. The device passed all the tests in Tables 1 and 2, below.

Table 1. Performance test results for the ProdiGI Traction Wire Device

Test	Description	Acceptance Criteria
Traction Wire Tensile Test	Test the mechanical integrity of the attached wire.	The grasper to wire tensile force should be above (b)(4) The crimp to wire tensile test must be above (b)(4)
Traction Grasper Tensile Test	Test the mechanical integrity of the grasper and components.	Introducer sheath to hub bond strength should be greater than (b)(4) The handle and deployment mechanism bonds including the following connections: - Proximal handle slider to crimp should have a tensile strength greater than (b)(4) - Tine puller/jaw seat to nitinol wire should have a tensile strength greater than (b)(4) Shaft to handle tensile strength must be greater than (b)(4)

Torque Test and Torque Stability and articulation	The user should be able to rotate the grasper vertically relative to the lesion and rotate it horizontally when grabbing the wire. Rotation of graspers allows for correct placement of the graspers on the anatomy.	Torque to rotate device should be less than (b)(4) in-oz. Bond must remain intact after being torqued in worst-case tortuosity. Graspers should be able to be rotated to four quadrants in worst case tortuosity. The angle of the colonoscope should not change by more than (b)(4) degrees in the fully retroflexed position after insertion of the device.
Insertion/Removal	Force required to insert and remove the device is less than or equal to the average person's ability to push or remove the device through the minimum compatible endoscope working channel.	The graspers must be able to be passed through a (b)(4) scope channel in tortuosity without damage to the scope channel as defined by generating macroscopic particulate. The graspers must be able to be passed through a (b)(4) scope channel in tortuosity without damage to any of the device components. The force to insert the 1st and 2nd graspers should be less than (b)(4) lbf. The 1st grasper sheath/introducer should not kink or buckle upon insertion into the scope. Removal of 1st and 2nd graspers should be less than (b)(4) lbf. The graspers must be able to be removed from a (b)(4) scope channel in tortuosity without damage to the scope channel as defined by generating macroscopic particulate.
Grasper Detachment	Evaluate the detachment forces of the graspers	Detachment Force of the 1st grasper to tissue must be above (b)(4) lbf. Detachment force of the 2nd grasper to tissue must be above (b)(4) lbf. The arms of the 2nd grasper should not come out of the capsule during grasper detachment from tissue. Force to remove the 2nd graspers from the tissue should be less than (b)(4) lbf.
Grasper Cycling Test	Test that the graspers of the traction devices can be opened and closed five times and still maintain their minimum opening span in simulated tortuosity.	Prior to deployment graspers must be able to be opened and closed (b)(4) and maintain their minimum opening span in simulated

		tortuosity. For the 1st grasper this is (b)(4) and for the 2nd grasper is (b)(4)
Wire lift force	The upward force of the traction wire was measured to assess that the force to lift tissue without pulling muscle into cutting plane was within specifications.	The traction wire should be able to produce (b)(4) lbf of upward force measured 10mm from the free end of the wire. The traction wire should be able to provide (b)(4) lbf of upward force after (b)(4) of being flattened and released. The lift force of the traction wire should be below (b)(4) lbf.
Deployment Force	The user must be able to deploy the graspers in order to place the traction device in an appropriate location.	The force to deploy graspers by squeezing the grasper handle should be greater than (b)(lbf ((b)(4) and less than (b)(4) lbf (b)(4) in tortuosity.
Traction Wire Tissue Test	Device should not cause mucosal laceration during use or removal of the device.	A standard ESD knife should not cause perforation in (b)(4 colon if the knife cuts through the wire during dissection. Device edges (deployed graspers, wire included wire after it is cut by knife, and crimp) should not cause mucosal laceration in explanted esophageal tissue when pulled through as an assembly.
Dimensional Inspection – Specification Assessment	Device conforms to dimensional specifications	The traction wire radius should be (b)(4) (b)(4) after assembly with the first grasper and deployment. The traction wire stance should be (b)(4) . The wire should be offered in flattened lengths of: (b)(4) The outer diameter of the graspers must be less than (b)(4) The working length of both graspers must be greater than or equal to (b)(4)

Table 2. Performance test results for the ProdiGI Traction Magnet Device

Test	Description	Acceptance Criteria
Traction Magnet Tensile Test	Test the mechanical integrity of the attached suture and magnet.	Force to remove the suture from the grasper to be ≥ (b)(4) lbf. Force to remove the magnet from the suture to be ≥ (b)(4) lbf. Force to separate crimp from suture to be ≥ (b)(4) lbf. Force to remove the magnet form the grasper body to be ≤ (b)(4) lbf.
Traction Grasper Tensile Test	Test the mechanical integrity of the grasper and components.	Introducer sheath to hub bond strength should be greater than (b)(4) lbf. The handle and deployment mechanism bonds, including the following connections: - Proximal handle slider to crimp tube should have a tensile strength greater than (b)(4) lbf. Shaft to handle tensile strength must be greater than (b)(4) lbf.
Torque Test and Torque Stability and articulation	Device can be rotated in worst case tortuosity to the desired position in order to successfully deploy the graspers.	Torque to rotate device should be less than (b)(4) in-oz. Bonds must remain intact after being torqued in worst case tortuosity. Graspers should be able to be rotated to four quadrants in worst case tortuosity. The angle of the colonoscope should not change by more than (b)(4) degrees in the fully retroflexed position after insertion of the device.
Insertion/Removal	Force required to insert and remove the device is less than or equal to the average person's ability to push or remove the device through the minimum compatible endoscope working channel.	The graspers must be able to be passed through a (b)(4) scope channel in tortuosity without damage to the scope channel as defined by generating macroscopic particulate. The device must be able to be passed through a 2.8 mm scope channel in tortuosity without any damage to any of the device components. The force to insert the device should be less than (b)(4) lbf.

		The introducer should not kink or buckle upon insertion into the scope. Removal of graspers should be less than (b)(4) lbf.
Grasper Detachment	Evaluate the detachment forces of the graspers	Force to remove the grasper from tissue to be ≥ (b)(4) lbf. The arms of the grasper should not come out of the capsule during grasper detachment from tissue. Force to remove the grasper from the tissue should be less than (b)(4) lbf.
Grasper Cycling Test	Test that the graspers of the traction devices can be opened and closed five times and still maintain their minimum opening span in simulated tortuosity.	Distance between grasper tines to be ≥ (b)(4) prior and after the grasper being opened and closed (b)(4)
Deployment Force	The user must be able to deploy the graspers in order to place the traction device in an appropriate location.	The force to deploy graspers by squeezing the grasper handle should be greater than (b)(lbf (b)(4) and less than (b)(4) lbf (b)(4)) in tortuosity.
Magnet Separation Force – Specification Assessment	The magnets must be able to readily join without becoming stuck to the deployment catheter.	Magnet to magnet strength to be < (b)(4) lbf (upper boundary of magnet separation). Magnet to magnet strength to be > (b)(4) lbf (lower boundary of magnet separation). Magnet to magnet strength to be < (b)(4) lbf with 4 magnets connected together.
Magnet Field Sensitivity	Evaluate the ability of the magnets to attract and assess magnetic field strength.	Magnets must join together at a minimum distance of (b)(4) Magnet field of the magnet to be ≤ (b)(4) at (b)(4) (b)(4)
Magnet Tissue Damage Test	Device should not cause mucosal laceration during use or removal of the device.	No signs of mucosal laceration upon retraction of the grasper.
Dimensional Inspection – Specification Assessment	Device conforms to dimensional specifications	Length for ERD-TMSM to be (b)(4) and for ER_TMLG (b)(4) The outer diameter of the grasper must be less than (b)(4). The working length of both graspers must be greater than or equal to (b)(4).

MAGNET SAFETY ASSESSMENT

The Traction Wire device uses a (b)(4) spherical magnet. Due to the potential for magnets to impact the function of electronic devices within a certain critical radius of a magnet, testing and analysis of the traction magnet device was conducted. The threshold magnetic field that will impact a pacemaker is 10 Gauss or 1 milli Tesla (mT). The results of such an event would be the external device entering magnet mode during which it may have reduced or altered performance while in the presence of the magnetic field. During an ESD procedure, up to a total of four magnets (two sets of graspers) can be used, making this the worst-case scenario in which a magnetic field would be present. (b)(4) groups of four magnets were scanned to determine the field strength data for the furthest point at which the measured filed was greater than (b)(4). Historical data was analyzed from a set of (b)(4) physically small patients with pacemakers to determine the worst-case distance from the esophagus to the pacemaker. Analysis for the critical radius using the worst-case scenario of four stacked magnets showed that the upper tolerance limit for the distance in which the magnet stack achieves (b)(4) is (b)(4). Analysis of the worst-case anatomical data shows that the lower tolerance limit of the distance from the esophagus to a pacemaker is (b)(4). Therefore, it is unlikely that the magnets of the traction magnet device would cause interference with other implanted devices.

USABILITY TESTING

Usability testing was provided to demonstrate the traction wire meets the user need/performance needs and has acceptable usability. Ex-vivo porcine and bovine tissue from the esophagus, stomach and colon was used for evaluation. All clinicians participating in the study were trained in standard ESD procedures, and clinicians with varying experience were selected to conduct the usability testing. Novice physicians were those with less than 3 years and/or less than 20 ESD cases to date, moderate physicians were those with 3-5 years of experience and/or 1-2 ESD cases per month, and skilled physicians were those with greater than 5 years of experience and three or more ESD cases per month.

For the traction wire, (b)(4) skilled, (b)(4) moderate and (b)(4) novice physicians participated in the study. Testing was compared between procedures with and without the use of the traction device. Testing included (b)(4) procedures in the esophagus, (b)(4) in the stomach and (b)(4) in the colon. (b)(4) procedures with the traction wire were done on (b)(4) lesions and (b)(4) procedures on (b)(4) lesions.

Visualization scores for the traction wire device were rated on a three-point scale where 1 = unacceptable, insufficient visualization/insufficient tissue lift; 2 = acceptable, clinically sufficient to perform procedure/sufficient tissue lift; 3 = exceeds expectations, visualization is an improvement over current clinical settings/exceptional tissue lift to aid in direct visualization of procedure.

Table 3 summarizes the results.

Table 3. Usability test results for the ProdiGI Traction Wire Device

Needs ID	Needs Statement	Acceptance Criteria	Sample Size	Results
N1.1	Device should provide endoscopic visualization of the submucosa space during entire dissection.	Average visualization score for dissection with traction wire ≥ average visualization score without traction wire	(b)(4) procedures with Traction and (b)(4) procedures without Traction (See Deviation 8.1)	**Visualization Score: PASS** Test: (b)(4) Control: (b)(4)
N1.2	Time to complete an ESD procedure with the device should be equivalent to or less than the time to complete an ESD procedure without the device.	Average procedure time (start of procedure to end of procedure) with traction device ≤ average procedure time without traction device	Min (b)(4) Procedures with Traction and (b)(4) Procedures without Traction (See Deviation 8.1)	**Procedure Time: PASS** Test: (b)(4) minutes Control: (b)(4) minutes
N1.3	Device should be able to be utilized in at least two of the following anatomical locations: the esophagus, stomach, and colorectal.	Minimum of 3 successful dissections (defined as complete resection of lesion) with Traction Wire in at least 2 organs	(b)(4) procedures each in esophagus, stomach, and colorectal	**Locations: PASS** (b)(4) in stomach (b)(4) in esophagus (b)(4) in colon
N1.4	Perforation rate during an ESD procedure with the device should be equivalent to or less than an ESD procedure without the device.	Perforation rate with traction device ≤ perforation rate without traction device	(b)(4) Procedures with Traction and (b)(4) Procedures without Traction (See Deviation 8.1)	**Perforation: PASS** (b)(4) perforations with test (b)(4) perforation with control
N1.5	Device should be able to provide adequate submucosal visibility for lesions sizes 2cm-5cm at a minimum.	Minimum of 3 successful dissections (defined as complete resection of lesion) with Traction Wire on 2 cm and 5 cm lesions	Min (b)(4) procedures with (b)(4) lesions Min (b)(4) procedures with (b)(4) lesions	**Lesion Size: PASS** (b)(4) procedures successfully completed with (b)(4) cm and (b)(4) procedures successfully completed with (b)(4) demonstrating the product functions over the designated range
N1.6	Device should not cause significant unintended trauma to the GI tract as defined by trauma that requires physician intervention using tools not already utilized during an ESD procedure.	No incidents of trauma from device that physician indicated they would intervene with tools not used in ESD procedure	(b)(4) procedures (See Deviation 8.2)	**Trauma: PASS** (b)(4) procedures completed with traction wire with no incidents of trauma noted
N1.7	Device should not introduce any new patient complications/serious adverse events that are not currently observed in an ESD procedure.	No incidents of complications that physician deems not typical for ESD procedure	(b)(4) procedures (See Deviation 8.2)	**Complications: PASS** (b)(4) procedures completed with traction wire with no incidents of complications

Note: The results for visualization score and procedure time are provided as mean ± standard deviation

For the traction magnet, two skilled, two moderate and two novice physicians participated in the study. Testing was compared between procedures with and without the use of the traction magnet device. Testing included (b)(4) procedures in the stomach and two in the colon. Four procedures with the traction wire were done on (b)(4) cm lesions and three procedures on (b)(4) cm lesions.

Visualization scores for the traction magnet device were rated on a five-point scale where 1 = unacceptable, 2 = poor, 3 = clinically acceptable, 4 = good, and 5 = exceeds expectations.

Table 4 summarizes the results.

Table 4. Usability test results for the ProdiGI Traction Magnet Device

Needs ID	Needs Statement	Acceptance Criteria	Sample Size	Results
N1.1	Device should provide endoscopic visualization of the submucosa space during entire dissection.	Average visualization score for dissection with traction magnet ≥ average visualization score without traction magnet	(b)(4) with Traction and (b)(4) without Traction	**Visualization Score: PASS** Test: (b)(4) Control: (b)(4)
N1.2	Time to complete an ESD procedure with the device should be equivalent to or less than the time to complete an ESD procedure without the device.	Average procedure time (start of procedure to end of procedure) with traction device ≤ average procedure time without traction device	(b)(4) with Traction and (b)(4) without Traction	**Procedure Time: PASS** Test: (b)(4) minutes Control: (b)(4) minutes** **Note: One Control case was terminated without completion due to poor visualization. This case had an infinite procedure time, so was could not be included in statistical analysis.
N1.3	Device should be able to be utilized in at least two of the following anatomical locations: the esophagus, stomach, and colorectal.	Minimum of (b)(4) successful dissections (defined as complete resection of lesion) with Traction Magnet in at least (b)(4) organs	Minimum (b)(4) each in stomach and colorectal	**Locations: PASS** (b)(4) in stomach tissue (b)(4) in colorectal tissue
N1.4	Perforation rate during an ESD procedure with the device should be equivalent to or less than an ESD procedure without the device.	Perforation rate with traction device ≤ perforation rate without traction device	(b)(4) with Traction and (b)(4) without Traction	**Perforation: PASS** Test: (b)(4) case with perforation which happened prior to Magnet deployment (1 case out of (b)(4) Control: (b)(4) cases with perforations and (b)(4) cases with muscle damage, but not through (b)(4) cases out of (b)(4)
N1.5	Device should be able to provide adequate submucosal visibility for lesions sizes (b)(4) at a minimum.	Minimum of (b)(4) successful dissections (defined as complete resection of lesion) with Traction Magnet on (b)(4) and (b)(4) lesions	Min (b)(4) with (b)(4) lesions Min (b)(4) with (b)(4) lesions	**Lesion Size: PASS** (b)(4) procedures successfully completed with (b)(4) cm and (b)(4) procedures successfully completed with (b)(4) cm demonstrating the product functions over the designated range

Needs ID	Needs Statement	Acceptance Criteria	Sample Size	Results
N1.6	Device should not cause significant unintended trauma to the GI tract as defined by trauma that requires physician intervention using tools not already utilized during an ESD procedure.	No incidents of trauma from device that physician indicated they would intervene with tools not used in ESD procedure	(b)(4)	**Trauma: PASS** (b)(4) procedures completed with traction magnet with no trauma that could not be treated with standard tools (perforation is expected ESD trauma)
N1.7	Device should not introduce any new patient complications/serious adverse events that are not currently observed in an ESD procedure.	No incidents of complications that physician deems not typical for ESD procedure	(b)(4)	**Complications: PASS** (b)(4) procedures completed with traction magnet with no incidents of complications not currently observed in ESD (perforation is expected ESD trauma)

*As defined in the protocol, statistical comparisons were made only between the (b)(4) test and (b)(4) control procedures. The (b)(4) and (b)(4) test procedures were not included in the comparison since there were no equivalent paired lesions for control.

Note: The results for visualization score and procedure time are provided as mean ± standard deviation

PERFORMANCE TESTING - ANIMAL

Animal studies evaluated ESD procedures using the traction wire and traction magnet devices compared to standard ESD (performed without traction devices) using live porcine models. Procedures were completed in the esophagus, stomach, and colon. The purpose of the GLP-compliant studies was to evaluate in vivo performance of the traction wire and traction magnet. The use of live animals was necessary to demonstrate performance of the device in perfused tissue, specifically with regards to assessing bleeding risk in comparison to the control treatment.

For the traction wire, the ERD-TW20 device was used as a representative model in animals based on size and anatomy of the animal, and it is representative of the ERD-TW35. For the traction magnet both the ERD-TMLG and ERD-TMSM were used for testing. Lesions of (b)(4) to (b)(4) cm were created based on suitability of anatomy to perform an ESD procedure. Procedure time was counted as the time the device was first inserted in the instrument channel until all the pieces were removed. Animals were then euthanized, and necropsy was performed.

(b)(4) animals were used for the traction wire testing, and (b)(4) animals were used for the traction magnet testing. Each animal was the subject of device procedures and control procedures, as outline in Table 5.

Table 5. Animal testing: Number of procedures for each device and tissue type

Tissue/Arm	Traction Wire	Control	Traction Magnet	Control
		(b)(4)		
Esophagus				
Stomach				
Colon				

The animal studies evaluated sufficient traction and visualization, lesion sizes, en bloc resection rate, perforation, tissue damage, procedure time and ease of use. Treatment sites were evaluated intraoperatively in terms of localized tissue trauma, including assessing for laceration, perforation and/or other tissue trauma. Assessment of endpoints were as follows:

- Bleeding: bleeding was assessed by study physicians intraoperatively via endoscopic visualization. A 6-point Likert scale was used where "0" was no bleeding and "5" was clinically unacceptable bleeding.

- Perforation: visible signs of perforation were assessed during the intraoperative procedure via endoscopic visualization. Assessments were recorded as yes or no. Upon completion of terminal procedures, treatment sites were assessed for signs of perforation at necropsy.

- Mucosal Laceration: visible signs of mucosal laceration with respect to each treatment site were assessed during the intraoperative procedure via endoscopic visualization. Upon completion of terminal procedures, treatment sites were assessed for signs of mucosal laceration at necropsy.

- Visualization: Visualization was assessed endoscopically by the physician at three time points, start of dissection, mid-dissection, and end of dissection. Visualization was characterized as the ability to view critical aspects and features of the target treatment site. Visualization was rated on a three-point scale where "1" was unacceptable, "2" acceptable, and "3" exceeds expectations.

- Ease of Removal: Physicians ranked the ability to remove all devices and tissue upon completion of the procedure. Ease of removal was rated on a three-point scale where "1" was unacceptable, "2" acceptable, and "3" exceeds expectations.

- Ease of Procedure: The physician was asked to provide feedback on how satisfied they were with the ease of completing the ESD procedure, time it took to complete the ESD procedure and observed traction during the submucosal dissection. A five-point scale was used where "1" was strongly disagree and "5" was strongly agree.

Table 6. Animal testing results for ProdiGI Traction Wire Device

Endpoint	Control Result (N=8)	Traction Wire Result (N=8)	Performance Comparison
Bleeding	(b)(4)		Traction better than Control
Perforation			Traction similar to Control
Laceration			Traction similar to Control
Ease of Removal			Traction similar to Control
Submucosal Visualization (Start)			Traction better than Control
Submucosal Visualization (Middle)			Traction better than Control
Submucosal Visualization (End)			Traction better than Control
Ease of Procedure (Easiness)			Traction better than Control
Ease of Procedure (Temporal)			Traction better than Control
Ease of Procedure (Effect)			Traction better than Control
Procedural Duration			Traction similar to Control

Note: All results in the table, except for perforation and laceration, are provided as mean ± standard deviation.

*All perforations were unrelated to the traction wire device use or design or the control procedure and resulted from complicated anatomy and fibrous tissue.

Table 7. Animal testing results for ProdiGI Traction Magnet Device

Endpoint	Control Result (N=8)	Traction Wire Result (N=8)	Performance Comparison
Bleeding	(b)(4)		Traction similar to Control
Perforation			Traction better than Control
Laceration			Traction similar to Control
Ease of Removal			Traction similar to Control
Submucosal Visualization (Start)			Traction better than Control
Submucosal Visualization (Middle)			Traction better than Control
Submucosal Visualization (End)			Traction better than Control
Ease of Procedure (Easiness)			Traction better than Control

Ease of Procedure (Temporal)	(b)(4)	Traction better than Control
Ease of Procedure (Effect)		Traction better than Control
Procedural Duration		Control better than Traction

Note: All results in the table, except for perforation and laceration, are provided as mean ± standard deviation.

For the traction wire device all assessment of endpoints showed the traction device performed better than the control or similar to the control. For the traction magnet device assessment of all endpoints except procedural time showed the traction device performed better than control or similar to control. For procedural time, the control performed better than the traction magnet. This is acceptable as deployment of the device is expected to take additional time.

Necropsy showed no visual evidence of laceration, and no other abnormalities were identified. Macroscopic features of the test treatment sites were comparable to the control treatment sties.

SUMMARY OF CLINICAL INFORMATION

No clinical data was provided.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The sponsor provided labeling that included the instructions for use and package labels. The instructions for use addresses the known hazards and risks of the device for the intended use and incorporates safety statements to mitigate these risks. The labeling includes safety instructions intended to minimize the risk of improper use of the ProdiGI device.

Important components of the labeling include:

The traction device should only be used by a physician trained in therapeutic endoscopy, including training in endoscopic submucosal dissections.

No portion of the device is intended to be an implant and the entire device must be removed at the end of the procedure.

Inclusion of tissue types in which the device has demonstrated to be effective.

The traction device must be used with concurrent endoscopic visualization.

The traction device should be used with caution in patients who present with anatomic variations of the targeted portion of the organ to be treated. Such disorders may include but are not limited to stricture.

Inclusion of the endoscopic specifications with which the traction device can be used with.

The traction device may be less effective in tissue with thin mucosa and fibrotic or other non-lifting tissue.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the endoscopic traction device and the measures necessary to mitigate these risks.

Table 8. Identified Risks to Health and Mitigation Measures

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	*In vivo* 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	*In vivo* performance testing Usability assessment

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

The risks of the device are based on data collected in animal studies described above and post-market complaint data. There is a risk of the graspers that are part of the traction devices not deploying on the target tissue or detaching from the tissue during the procedure. The probability of such events is low and occurrence can be managed with sufficient instructions. Additional traction devices can be used if a grasper does not deploy properly or if a grasper detaches during the procedure. No bleeding was seen in the procedures completed in animals using the traction device compared to one case of bleeding seen in the control group. One case of perforation was noted in both the control group and traction group. This perforation was identified as being unrelated to use of the traction device or control procedure and was from complicated anatomy and fibrous tissue. The perforations occurred during the circumferential cut made at the start of the ESD procedure prior to grasper deployment and lesion resection.

The probable benefits of the device are also based on data collected in animal studies described above. The animal studies demonstrated use of the traction device provides sufficient traction and visualization when compared to the control group where procedures were performed with no traction device. Use of the traction device also does not require the use of multi-channel scopes or additional accessories to perform the procedure. This increases the ease of use of the device as demonstrated by the ease-of-use scores provided by physicians for the procedures completed with the traction device and without the traction device.

PATIENT PERSPECTIVES

This submission did not include specific information on patient perspectives for this device.

BENEFIT/RISK CONCLUSION

In conclusion, given the available information above, for the following indication statement:

> 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.

The probable benefits outweigh the probable risks for the ProdiGI. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the ProdiGI is granted and the device is classified as follows:

> Product Code: QSW
> Device Type: Endoscopic traction device
> Regulation Number: 21 CFR 876.4410
> Class: II