November 3, 2023

Actuated Medical, Inc.
Douglas Dillon
Director, Quality Assurance & Regulatory Affairs
320 Rolling Ridge Drive
Bellefonte, Pennsylvania 16823

Re: K231254
Trade/Device Name: GripTract-GI Endoscopic Tissue Manipulator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF
Dated: October 6, 2023
Received: October 6, 2023

Dear Douglas Dillon:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231254

Device Name
Griptract-GI Endoscopic Tissue Manipulator

Indications for Use *(Describe)*
The GripTract-GI Endoscopic Tissue Manipulator (GripTract) is an accessory intended to assist in positioning the distal end of an endoscope from the mucosal surface and assist with optical visualization, diagnosis, and endoscopic treatment.

GripTract is indicated for use in the large intestine with any standard endoscope that has a distal tip outer diameter of 11.5 – 12.0 mm and working length of 168 – 170 cm.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K231254 510(k) SUMMARY

Applicant Information

Date Prepared: October 6, 2023

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Device Information

Trade Name	GripTract-GI™ Endoscopic Tissue Manipulator
Common Name:	GripTract-GI™ Endoscopic Tissue Manipulator
Classification:	21 CFR §876.1500
Classification Name:	Endoscope and accessories
Product Code:	FDF

Predicate & Reference Devices

Type	510(k) Number	Trade Name	Submitter
Predicate Device	K210851	DiLumen Endolumenal Interventional Platform (DiLumen)	Lumendi Ltd.
Reference Device	K984358	D-201-12704 Disposable Distal Attachment	Olympus Americas, Inc.

Device Description

GripTract is a single-use, non-sterile, endoscope accessory intended to ensure complete positioning of an endoscope and assist with optical visualization, diagnosis, and endoscopic treatment. It is indicated for use in the large intestine with any standard endoscope that has a distal tip outer diameter of 11.5 – 12.0 mm and a working length of 168 – 170 cm.

The GripTract Handpiece attaches to the endoscope control body just below the working channel. The soft End Cap with two integrated Fingers for tissue manipulation is placed on the distal end of the endoscope. Two Control Knobs in the Handpiece each operate a corresponding Finger, permitting the User to rotate and extend/retract the Fingers for tissue manipulation and visualization independent of the endoscope's movement or the presence of other tools in the endoscope's working channel.

Indications for Use

The GripTract-GI Endoscopic Tissue Manipulator (GripTract) is an accessory intended to assist in positioning the distal end of an endoscope from the mucosal surface and assist with optical visualization, diagnosis, and endoscopic treatment.

GripTract is indicated for use in the large intestine with any standard endoscope that has a distal tip outer diameter of 11.5 – 12.0 mm and working length of 168 – 170 cm.

Technological Characteristics

The table below provides a comparison of the technological characteristics of the two devices. Many items, including intended use, user population, and anatomical area of use are identical. Key differences include method of manipulating tissue, method of attaching controls to endoscope, and materials of construction; none of which raise different questions of safety and efficacy as compared to the Predicate Device.

Category	Predicate DiLumen	Proposed GripTract	Comparison
Intended / Indications for use	The Lumendi DiLumen is an accessory to an endoscope. The DiLumen dual balloon accessory is intended for use with any standard endoscope that has a distal tip outer diameter of 12.5 - 14.3 mm. The device is indicated to ensure complete positioning of an endoscope during navigation in the large intestine, while assisting with optical visualization, diagnosis, tissue manipulation, and endoscopic treatment.	GripTract is an accessory intended to assist in positioning the distal end of an endoscope from the mucosal surface and assist with optical visualization, diagnosis, and endoscopic treatment. The device is indicated for use in the large intestine with any standard endoscope that has a distal tip outer diameter of 11.5 – 12.0 mm and a working length of 168-170 cm.	Same – intended use is the same. Indications differ only by the specific endoscope dimensions. GripTract is designed for smaller diameter endoscopes with the same length as one specific model of the Predicate.

Category	Predicate DiLumen	Proposed GripTract	Comparison
Compatible Endoscope OD	Standard endoscope with diameter 12.5-14.3 mm	Standard endoscope with diameter 11.5-12.0 mm	Different – GripTract designed for endoscopes with smaller OD.
Working Length	168 cm (different models for different length endoscopes)	168-170 cm	Same
Sterility	DiLumen is a non-sterile device that does not require cleaning or sterilization prior to use.	GripTract is a non-sterile device that does not require cleaning or sterilization prior to use.	Same
Single Use/reusable	Single Use	Single Use	Same
Shelf Life	24 months	24 months	Same
Distal End Attachment Method	Close-fitting sleeve fits securely over the distal end of the endoscope.	Low durometer End Cap fits securely onto the distal end of the endoscope.	Same
Proximal Control Attachment Method	Endoscope is placed through the Device Lock then a radial knob is twisted to tighten the Device Lock securing the DiLumen controls in the same plane as the endoscope controls.	O-Rings wrap around endoscope control body securing the GripTract controls in the same plane as the endoscope controls.	Different – both attachment methods securely hold the device onto the endoscope control body and place controls in the same location.

Category	Predicate DiLumen	Proposed GripTract	Comparison
Operating Principle	DiLumen is secured to the endoscope at both the distal and proximal ends. The User manipulates the DiLumen controls with the same hand as the endoscope controls. The Fore Balloon can be inflated, extended, and retracted to improve endoscopic visualization and treatment.	GripTract is secured to the endoscope at both the distal and proximal end. The User manipulates the GripTract controls with the same hand as the endoscope controls. The Fingers can be rotated, extended, and retracted to improve endoscopic visualization and treatment.	Same

Category	Predicate DiLumen	Proposed GripTract	Comparison
Tissue Manipulation	Tissue is manipulated using the Controls to inflate and deflate the Fore and Aft Balloons, which maintain position of or in tissue. The Fore Balloon with Suture Loops can also be extended and retracted to enhance endoscopic visualization and treatment. Attaching tissue to the Suture Loops allows lifting and retraction of tissue.	Tissue is manipulated using the Controls to extend, retract, and rotate the coated Fingers to enhance endoscopic visualization and treatment. The Fingers can be used to directly lift and retract tissue, and to help guide working tools.	Different – tissue manipulation tools are different, but both physically manipulate/retract tissue as needed in order to facilitate visualization and diagnosis / treatment in the gastrointestinal tract.
Accessories	DiLumen can be used with various additional endoscope accessories but is not supplied with any designated accessories.	GripTract can be used with various additional endoscope accessories but is not supplied with any designated accessories.	Same

Category	Predicate DiLumen	Proposed GripTract	Comparison
Biocompatibility Testing	Biocompatibility tested per ISO 10993-1: Cytoxicity, Sensitization, Irritation, Systemic Toxicity, Pyrogenicity, and EO Residuals (**Note**: Predicate is NOT sterile)	Biocompatibility tested per ISO 10993-1: Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, and Pyrogenicity (**Note**: Proposed is NOT sterile)	Different – additional test performed by Predicate is not relevant to non-sterile devices.
Disposal	Dispose of the DiLumen in accordance with accepted medical practice and local, state, and federal regulations for a single use medical device disposal.	Dispose of the GripTract in accordance with accepted medical practice and local, state, and federal regulations for a single use medical device disposal.	Same
Use Environment	Clinical surgical settings (e.g., hospital, outpatient care facility) where endoscopic procedures are performed.	Clinical surgical settings (e.g., hospital, outpatient care facility) where endoscopic procedures are performed.	Same

Category	Predicate DiLumen	Proposed GripTract	Comparison
User Population	Medical specialists who have proper training and competencies in endoscopic procedures and endoscopic equipment.	Medical specialists who have proper training and competencies in endoscopic procedures and endoscopic equipment.	Same
Anatomic Area of Use	Natural orifice for access to colon.	Natural orifice for access to colon.	Same
Materials of Construction	**Sleeve**: Pellathane (polyurethane) with 2.5% Glycolube **Balloon**: polyurethane **Inflation Tube/Push Rods**: Isoplast (polyurethane), Pebax (polyether block amide), Pellathane (polyurethane)	**End Cap**: polyurethane, polycarbonate **Sheath**: PTFE (polytetrafluoroethylene) **Fingers**: ETFE (ethylene tetrafluoroethylene) coated stainless steel **Torque Tubes**: stainless steel	Different – GripTract uses different biocompatible polymeric materials and also uses stainless steel to ensure effective force transmission.

Non-Clinical Performance Data

The methods and performance data for evaluating the technological differences and questions of safety and effectiveness include bench performance testing, usability testing, biocompatibility testing, and in vivo porcine testing. This testing is summarized in the table below.

Bench Performance Testing: Verification of Product Specification testing confirmed that GripTract met all product specifications and acceptance criteria in ambient, high temperature/humidity, and low temperature environmental conditions. Distribution testing conforming to ASTM D4169-

16 (FDA Recognition Number 14-499) confirmed that GripTract met all product specifications and acceptance criteria after being exposed to simulated shipping and transportation conditions. Accelerated Shelf-Life testing confirmed that GripTract met all product specifications and acceptance criteria after exposure to conditions simulating a shelf-life of two years. Reliability testing confirmed that GripTract met all product specifications and acceptance criteria following worst-case simulated use. Bench Safety testing confirmed that GripTract is sufficiently safe during benchtop evaluations that approximate worst-case scenarios and interactions that may occur between biological tissue and the GripTract Fingers. A comparison of the endoscope viewing area between GripTract and the Reference Device confirmed that GripTract does not block visualization relative to a standard distal end cap.

Usability Testing: GripTract was tested with two different user populations based on their interactions with the device, and the tasks and responsibilities they perform. Specifically, there is a user population for setting up the device and another for actually using the device clinically with the Patient. Human factors validation testing of both user populations and tasks confirmed GripTract can safely and effectively be set-up and used for its intended use in the expected use environment without encountering serious use errors or other problems.

Biocompatibility Testing: GripTract is categorized as a surface device contacting breached or compromised surfaces for a limited duration. Cytotoxicity, sensitization, irritation, acute systemic toxicity, and material mediated pyrogenicity testing was conducted on GripTract in its final finished form. All tests confirmed the suitability of GripTract.

Porcine Testing: Worst-case procedures completed with GripTract exhibited equivalent visual and histological mucosal damage compared to endoscope-only (control) procedures and there were no device-attributable adverse events at either acute or chronic time points. This demonstrates that GripTract is safe and effective for its intended use.

Summary of non-clinical performance testing.			
Test Performed	**Test Description**	**Standards Organization and Designation**	**Results**
Verification of Product Specification	Verification of Product Specifications after exposure to ambient, high temp, and low temperature environmental conditions.	NA	Pass
Distribution	Confirmation of Product Specifications following exposure to simulated distribution stress and conditions.	ASTM D4169-16	Pass
Accelerated Shelf Life	Confirmation of Product Specifications following exposure to accelerated conditions simulating a shelf-life of two years.	NA	Pass
Shelf Life	Confirmation of Product Specifications following exposure to real-time ambient conditions for two years.	NA	Test is on-going.
Reliability	Confirmation of Product Specifications following worst-case simulated use.	NA	Pass
Bench Safety	Assessed safety of worst-case interactions between biological tissue and GripTract Fingers.	NA	Pass
Usability (Set-Up)	A total of 15 Users assessed whether the intended user population can successfully set up GripTract without serious use errors, failure to perform critical tasks, or encountering problems that affect the intended use and expected use environment.	NA	Pass
Usability (Use)	A total of 15 Users assessed whether the intended user population can successfully use GripTract without serious use errors, failure to perform critical tasks, or encountering problems that affect the intended use and expected use environment.	NA	Pass
Biocompatibility	Final, finished devices tested for cytotoxicity, sensitization, irritation, acute systemic toxicity, and material mediated pyrogenicity.	ISO 10993-12 ISO 10993-5 ISO 10993-10 ISO 10993-23 IOS 10993-11	Pass
Porcine Testing	In vivo porcine testing GripTract against standard of care in worst-case procedure. Acute and chronic time points examined for differences in visual and histological mucosal damage as well as presence of device-attributable adverse events.	NA	Pass

Conclusions

After evaluating GripTract for its intended use, then identifying, evaluating, and mitigating the risks associated with both use and foreseeable misuse, it is concluded that GripTract is substantially equivalent to DiLumen when used as indicated to assist in positioning the distal end of an endoscope from the mucosal surface and assist with optical visualization, diagnosis, and endoscopic treatment.