October 4, 2024

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

Re: K242325
Trade/Device Name: GripTract-GI Endoscopic Tissue Manipulator Lower GI Models
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDF
Dated: August 2, 2024
Received: August 6, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Sivakami Venkatachalam -S

for
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242325

Device Name

GripTract-GI Endoscopic Tissue Manipulator Lower GI Models

Indications for Use *(Describe)*

The GripTract-GI Endoscopic Tissue Manipulator (GripTract) Lower GI Models are accessories 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 Lower GI Models are indicated for use in the large intestine with any standard endoscope as follows:

Endoscope Distal Tip Outer Diameter (mm)	Endoscope Working Length (cm)	GripTract Model #
12.8 - 13.3	168 - 170	GT-CL170
12.8 - 13.3	130 - 133	GT-CL130
11.5 - 12.0	168 - 170	GT-CM170
11.5 - 12.0	130 - 133	GT-CM130

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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+ ISO 13485:2016
+ Medical Device Single Audit Program (MDSAP)
+ Women's Business Enterprise (WBE)
+ Women-Owned Small Business (WOSB)

K242325 510(k) SUMMARY

Applicant Information

Date Prepared: October 1, 2024

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Contact Person: Douglas R. Dillon
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Device Information

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

Predicate Device

510(k) Number	Trade Name	Submitter
K231254	GripTract-GI™ Endoscopic Tissue Manipulator (Model GT-101)	Actuated Medical, Inc.

Device Description

The GripTract-GI™ Endoscopic Tissue Manipulator (GripTract) Lower GI Models are disposable, non-sterile accessories intended to assist in positioning the distal end of an endoscope from the mucosal surface and assist with optical visualization, diagnosis, and endoscopic treatment. There are four (4) different GripTract Lower GI Models (GT-CL170, GT-CL130, GT-CM170, and GT-CM130) which are indicated for use in the large intestine with standard endoscopes that have specific tip outer diameters and working lengths.

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) Lower GI Models are accessories 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 Lower GI Models are indicated for use in the large intestine with any standard endoscope as follows:

Endoscope Distal Tip Outer Diameter (mm)	Endoscope Working Length (cm)	GripTract Model #
12.8 – 13.3	168 – 170	GT-CL170
12.8 – 13.3	130 – 133	GT-CL130
11.5 – 12.0	168 – 170	GT-CM170
11.5 – 12.0	130 – 133	GT-CM130

Technological Characteristics

The GripTract Lower GI Models and Predicate Device have the same intended use, user population, and anatomical area of use as well as nearly identical designs. The GripTract Lower GI Models do have different technological characteristics including dimensional changes, torque tube design changes, and differences in materials of construction. The table below provides a comparison of the technological characteristics of the Predicate Device and GripTract Lower GI Models:

<table>
<tr><th colspan="4">Comparison of Predicate and GripTract Lower GI Models</th></tr>
<tr><th>Category</th><th>Predicate GripTract Model GT-101</th><th>GripTract Lower GI Models</th><th>Comparison</th></tr>
<tr><td>Indications for Use</td><td>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.</td><td>The GripTract-GI Endoscopic Tissue Manipulator (GripTract) Lower GI Models are accessories 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 Lower GI Models are indicated for use in the large intestine with any standard endoscope as follows:
<table>
<tr><th>Distal Tip Outer Diameter (mm)</th><th>Working Length (cm)</th><th>Model #</th></tr>
<tr><td>12.8 - 13.3</td><td>168 - 170</td><td>GT-CL170</td></tr>
<tr><td>12.8 - 13.3</td><td>130 - 133</td><td>GT-CL130</td></tr>
<tr><td>11.5 - 12.0</td><td>168 - 170</td><td>GT-CM170</td></tr>
<tr><td>11.5 - 12.0</td><td>130 - 133</td><td>GT-CM130</td></tr>
</table></td><td>Different – intended use is the same. GripTract Lower GI Models are designed for endoscopes with the same or larger diameter and the same or shorter length than the Predicate Model. The Indications for Use differ only by the specific endoscope dimensions.</td></tr>
<tr><td>Compatible Endoscope OD and Working Lengths</td><td>GT-101:
OD: 11.5 – 12.0 mm
Length: 168 – 170 cm</td><td>GT-CL170:
OD: 12.8 – 13.3 mm
Length: 168 – 170 cm

GT-CL130:
OD: 12.8 – 13.3 mm
Length: 130 – 133 cm

GT-CM170:
OD: 11.5 – 12.0 mm
Length: 168 – 170 cm

GT-CM130
OD: 11.5 – 12.0 mm
Length: 130 – 133 cm</td><td>Different – Predicate Device and Model GT-CM170 have identical endoscope compatibility. Additional Lower GI Models are compatible with an expanded range of endoscopes.</td></tr>
</table>

Comparison of Predicate and GripTract Lower GI Models			
Category	**Predicate GripTract Model GT-101**	**GripTract Lower GI Models**	**Comparison**
Finger Design	Stainless steel Fingers with electrically insulative ETFE (ethylene tetrafluoroethylene) coating.	Stainless steel Fingers with electrically insulative ETFE (ethylene tetrafluoroethylene) coating.	Different – smaller diameter stainless steel rod for Fingers permit a smaller overall diameter for the End Cap.
End Cap Diameter	**GT-101:** 22.0 mm (0.865 in) OD 9.83 mm (0.387 in) ID	**GT-CM130 & CM170:** 19.65 mm (0.772 in) OD 10.59 mm (0.417 in) ID **GT-CL130 & CL170:** 21.25 mm (0.835 in) OD 12.19 mm (0.480 in) ID	Different – All GripTract Lower GI Models have smaller End Cap diameters than the Predicate.
Torque Tube Design	Uniform flexibility along entire length of device.	Distal 20 cm (8 in) of GripTract Lower GI Models is more flexible. The remaining proximal length is identical to Predicate Device.	Different – Distal 8 inches of GripTract Lower GI Models utilize different design and materials to allow greater flexibility in the region of the endoscope's bending section.
Sheath	extruded Polytetrafluoroethylene (PTFE)	expanded Polytetrafluoroethylene (ePTFE)	Different – GripTract Lower GI Models use expanded PTFE with slightly different ID and OD. In addition, the GripTract Lower GI Models CM130 and CL130 are shorter in length to accommodate shorter endoscopes.

Comparison of Predicate and GripTract Lower GI Models			
Category	**Predicate GripTract Model GT-101**	**GripTract Lower GI Models**	**Comparison**
Materials of Construction	**End Cap**: polyurethane, polycarbonate **Sheath**: PTFE (polytetrafluoroethylene) **Fingers**: ETFE (ethylene tetrafluoroethylene) coated stainless steel **Torque Tubes**: stainless steel **O-Rings:** Viton	**End Cap**: polyurethane, polycarbonate **Sheath**: ePTFE (expanded polytetrafluoroethylene) **Fingers**: ETFE (ethylene tetrafluoroethylene) coated stainless steel **Torque Tubes**: stainless steel **O-Rings:** Buna-N **Shrink Tubing:** PVDF (polyvinylidene fluoride)	Different – GripTract Lower GI Models use different polymeric materials for the Sheath, O-Rings, and distal Torque Tube assemblies.
Tissue Manipulation with Control Knobs	Tissue is manipulated using the Control Knobs 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. Each Control Knob has a colored indicator that matches the color (blue or gray) of the Finger that the Control Knob manipulates and is printed with an arrow to help identify which direction that Finger's tip is facing.	Tissue is manipulated using the Control Knobs 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. Each Control Knob has a colored indicator that matches the color (blue or gray) of the Finger that the Control Knob manipulates.	Different – Identical in every respect except that the printed arrow on each Control Knob's colored indicator has been removed in the GripTract Lower GI Models.
Biocompati-bility Testing	Biocompatibility tested per ISO 10993-1: • Cytotoxicity • Sensitization • Irritation • Systemic Toxicity • Pyrogenicity	Biocompatibility tested per ISO 10993-1: • Cytotoxicity • Sensitization • Irritation • Systemic Toxicity • Pyrogenicity	Same
Distal End Attachment Method	Low durometer End Cap fits securely onto the distal end of the endoscope.	Low durometer End Cap fits securely onto the distal end of the endoscope.	Same
Sterility	Non-sterile device that does not require cleaning or sterilization prior to use.	Non-sterile device that does not require cleaning or sterilization prior to use.	Same

Comparison of Predicate and GripTract Lower GI Models			
Category	**Predicate GripTract Model GT-101**	**GripTract Lower GI Models**	**Comparison**
Single - Use/reusable	Single-Use	Single-Use	Same
Shelf Life	24 months	24 months	Same
Operating Principle	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.	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
Accessories	GripTract 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
Disposal	Dispose of the GripTract in accordance with accepted medical practice and local, state, and federal regulations for single-use medical device disposal.	Dispose of the GripTract in accordance with accepted medical practice and local, state, and federal regulations for 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
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

Non-Clinical Performance Data

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

Summary of non-clinical performance testing.		
Test Performed	**Test Description**	**Results**
Verification of Product Specification	Verification of Product Specifications after exposure to ambient, high temperature, and low temperature environmental conditions.	Pass
Reliability	Confirmation of Product Specifications following exposure to worst-case simulated use.	Pass
Bench Safety	Assessed safety of worst-case interactions between biological tissue and GripTract Lower GI Model Fingers.	Pass
Torsional Fatigue Strength	Confirmation of Products Specifications following exposure to repeated worst-case torsional load.	Pass
Torque Comparison	Comparison of the force transmitted to the Finger by different GripTract Lower GI Models.	Equivalent force transmission
End Cap Force Comparison	Comparison of the force required to remove the End Caps of different GripTract Lower GI Models.	Removal forces exceed reported maximum pull forces in colonoscopies
Accelerated Shelf Life	Confirmation of Product Specifications following exposure to accelerated conditions simulating a shelf life of two years.	Pass
Shelf Life	Confirmation of Product Specifications following exposure to real-time ambient conditions for two years.	Test is on-going
Biocompatibility	Final, finished devices tested in accordance with ISO 10993-1. Testing included cytotoxicity, sensitization, irritation, systemic toxicity, and pyrogenicity.	Pass

Bench Performance Testing: Verification of Product Specification testing confirmed that GripTract Lower GI Models met all product specifications and acceptance criteria in

ambient, high temperature/humidity, and low temperature environmental conditions. Reliability testing confirmed that they met all product specifications and acceptance criteria following worst-case simulated use. Bench Safety testing confirmed that they are sufficiently safe during benchtop evaluations that approximate worst-case scenarios and interactions that may occur between biological tissue and the GripTract Lower GI Model Fingers. Torsional Fatigue Strength testing confirmed that GripTract Lower GI Models met all product specifications and acceptance criteria following repeated worst-case torsional load. Torque Comparison testing demonstrated that the force transmission capabilities of the two GripTract Lower GI Models at the dimensional extremes of the product line are equivalent. End Cap Force Comparison testing demonstrated the forces required to remove the End Caps under worst-case conditions exceed the reported maximum pull forces in colonoscopies. Accelerated Shelf Life testing confirmed that they met all product specifications and acceptance criteria after exposure to conditions simulating a shelf life of two years. A comparison of the endoscope viewing area between the Predicate Device and GripTract Lower GI Models confirmed that the GripTract Lower GI Models do not block visualization.

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

Conclusions

After evaluating GripTract Lower GI Models for their intended use, then identifying, evaluating, and mitigating the risks associated with use, foreseeable misuse, and the technological differences between the Predicate Device, it is concluded that the GripTract Lower GI Models are as safe and effective as GripTract Model GT-101 when used as indicated to ensure complete positioning of an endoscope and assist with optical visualization, diagnosis, and endoscopic treatment.