October 31, 2025

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

Re: K251041
Trade/Device Name: GripTract-GI Endoscopic Tissue Manipulator (GT-GS100)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS
Dated: April 2, 2025
Received: October 2, 2025

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251041

Please provide the device trade name(s).

GripTract-GI™ Endoscopic Tissue Manipulator Upper GI Model GT-GS100

Please provide your Indications for Use below.

The GripTract-GI Endoscopic Tissue Manipulator (GripTract) Upper GI Model 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 Upper GI Model is indicated for use in the upper gastrointestinal tract with any standard endoscope as follows:

Endoscope Distal Tip Outer Diameter (mm)	Endoscope Working Length (cm)	GripTract Model #
9.8 - 10.5	103 - 110	GT-GS100

Please select the types of uses (select one or both, as applicable).

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

K251041 510(k) SUMMARY

Applicant Information

Date Prepared: September 30, 2025

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Director, Quality Assurance and Regulatory Affairs
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f: (814) 355-1523
Email: Douglas.Dillon@actuatedmedical.com

Device Information

Trade Name	GripTract-GI™ Endoscopic Tissue Manipulator Upper GI Model GT-GS100
Common Name:	GripTract-GI™ Endoscopic Tissue Manipulator Upper GI Model GT-GS100
Classification:	21 CFR §876.1500
Classification Name:	Endoscope and accessories
Product Code:	FDS

Predicate Device

Trade Name	GripTract-GI™ Endoscopic Tissue Manipulator Lower GI Models
510(k) Number	K242325
Submitter	Actuated Medical, Inc.

Device Description

The GripTract-GI™ Endoscopic Tissue Manipulator (GripTract) Upper GI Model GT-GS100 is a disposable, non-sterile 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 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 on 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) Upper GI Model 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 Upper GI Model is indicated for use in the upper gastrointestinal tract with any standard endoscope as follows:

Endoscope Distal Tip Outer Diameter (mm)	Endoscope Working Length (cm)	GripTract Model #
9.8 – 10.5	103 – 110	GT-GS100

Technological Characteristics

GripTract Upper GI Model GT-GS100 and the Predicate Device have the same intended use, user population, and nearly identical designs. GripTract Upper GI Model GT-GS100 has a different anatomical area of use – upper gastrointestinal (GI) tract versus large intestine – and has different technological characteristics required to accommodate the different endoscopes used in the upper GI; including dimensional changes and revised packaging. The table below provides a comparison of the technological characteristics of the Predicate GripTract Lower GI Model GT-CM130 and GripTract Upper GI Model GT-GS100. The GripTract Lower GI Model GT-CM130 is dimensionally the closest of the Predicate Device models to the Proposed Device.

<table>
<tr><th colspan="4">Comparison of Predicate and Proposed GripTract Upper GI Model GT-GS100.</th></tr>
<tr><th>Category</th><th>Predicate GripTract Model GT-CM130</th><th>Proposed GripTract Model GT-GS100</th><th>Comparison</th></tr>
<tr><td>Intended / Indications for Use</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>Endoscope Distal Tip Outer Diameter (mm)</th><th>Endoscope Working Length (cm)</th><th>GripTract 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>The GripTract-GI Endoscopic Tissue Manipulator (GripTract) Upper GI Model 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 Upper GI Model is indicated for use in the upper gastrointestinal tract with any standard endoscope as follows:
<table>
<tr><th>Endoscope Distal Tip Outer Diameter (mm)</th><th>Endoscope Working Length (cm)</th><th>GripTract Model #</th></tr>
<tr><td>9.8 – 10.5</td><td>103 - 110</td><td>GT-GS100</td></tr>
</table></td><td>Different – although intended use is the same, the Indications for Use differ by anatomical area of use and the specific endoscope dimensions.</td></tr>
<tr><td>Anatomical Area of Use</td><td>Large intestine.</td><td>Upper gastrointestinal tract.</td><td>Different – Proposed Device is used in upper gastrointestinal tract, while Predicate is used in lower gastrointestinal tract.</td></tr>
<tr><td>Compatible Endoscope OD and Working Lengths</td><td>GT-CM130
OD: 11.5 – 12.0 mm
Length: 130 – 133 cm</td><td>GT-GS100
OD: 9.8 – 10.5 mm
Length: 103 – 110 cm</td><td>Different – Proposed Device is compatible with endoscopes that have smaller diameter and shorter length than the Predicate Device.</td></tr>
</table>

Comparison of Predicate and Proposed GripTract Upper GI Model GT-GS100.			
Category	**Predicate GripTract Model GT-CM130**	**Proposed GripTract Model GT-GS100**	**Comparison**
End Cap Diameters	**GT-CM130:** 19.65 mm (0.772 in) OD 10.59 mm (0.417 in) ID	**GT-GS100:** 18.31 mm (0.721 in) OD 9.30 mm (0.366 in) ID	Different – Proposed Device has smaller inside and outside diameters than the Predicate to accommodate smaller endoscopes.
Finger Construction & Design	Stainless steel Fingers with electrically insulative ETFE (ethylene tetrafluoroethylene) coating.	Stainless steel Fingers with electrically insulative ETFE (ethylene tetrafluoroethylene) coating.	Different – curved portion of Finger is 2.5 mm shorter on Proposed Device.
Torque Tube Design & Length	Stainless steel torque transmission components with more flexible distal 20 cm (8 in) portion.	Stainless steel torque transmission components with more flexible distal 20 cm (8 in) portion.	Different – The Torque Tube design is identical, but the Proposed Device's proximal portion is shorter in length to accommodate shorter endoscopes.
Sheath	expanded Polytetrafluoroethylene (ePTFE).	expanded Polytetrafluoroethylene (ePTFE).	Different – The Sheath design is identical, but the Proposed Device's Sheath is shorter in length to accommodate shorter endoscopes.
Packaging	Individual GripTract devices placed in thermoformed copolyester tray and sealed within Tyvek/LDPE pouches. Five pouches in one corrugated carton.	Individual GripTract devices placed in thermoformed copolyester tray and sealed within Tyvek/LDPE pouches. Five pouches in one corrugated carton.	Different – Additional pocket added to thermoformed tray to accommodate shorter length of Proposed Device.

Comparison of Predicate and Proposed GripTract Upper GI Model GT-GS100.			
Category	**Predicate GripTract Model GT-CM130**	**Proposed GripTract Model GT-GS100**	**Comparison**
Materials of Construction	**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).	**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).	Same.
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.	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.	Same.
Biocompatibility 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 – Biocompatibility testing provided for the Predicate Device remains valid for the Proposed Device.
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.
Single - Use/Reusable	Single-Use.	Single-Use.	Same.

Comparison of Predicate and Proposed GripTract Upper GI Model GT-GS100.			
Category	**Predicate GripTract Model GT-CM130**	**Proposed GripTract Model GT-GS100**	**Comparison**
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.

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.
Bench Safety	Assessed safety of worst-case interactions between biological tissue and GripTract Upper GI Model GT-GS100 Fingers.	Pass.
Torque Comparison	Comparison of the force transmitted to the Finger by the Predicate and Proposed Devices.	Pass.
End Cap Removal Force	Measured the force required to remove the End Cap from worst-case endoscope.	Pass.
Reliability	Confirmation of Product Specifications following exposure to worst-case simulated use.	Pass.
Torsional Fatigue Strength	Confirmation of Products Specifications following exposure to repeated worst-case torsional load.	Pass.
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	Tested in accordance with ISO 10993-1. Testing included cytotoxicity, sensitization, irritation, systemic toxicity, and pyrogenicity.	Pass.

Summary of non-clinical performance testing.		
Test Performed	**Test Description**	**Results**
Working Length	Measured working length and confirmed devices meet design tolerance.	Pass.
Finger Curved Portion Length	Measured curved portion of Finger and confirmed components meet design tolerance.	Pass.
Finger Maneuver	Confirmed that performance criteria are met when performing eight maneuvers on three different flap geometries in ex vivo porcine tissue.	Pass.

Bench Performance Testing: Verification of Product Specification testing confirmed that GripTract Upper GI Model GT-GS100 met all product specifications and acceptance criteria in ambient, high temperature/humidity, and low temperature environmental conditions. Bench Safety testing confirmed that Upper GI Model GT-GS100 is safe during benchtop evaluations that approximate worst-case scenarios and interactions that may occur between biological tissue and the GripTract Upper GI Model GT-GS100 Fingers. Torque Comparison testing demonstrated that Upper GI Model GT-GS100 produces lower forces at the Finger than the Predicate Device when the same torque is applied to the Control Knobs. This demonstrated that tests performed on the Predicate Device were performed using the worst-case model and remain valid for the Proposed Device. End Cap Removal Force testing demonstrated that the forces required to remove the Upper GI Model GT-GS100 End Caps under worst-case conditions exceed the reported maximum pull forces in colonoscopies. Reliability testing confirmed that GripTract met all product specifications and acceptance criteria following worst-case simulated use. Torsional Fatigue Strength testing confirmed that GripTract met all product specifications and acceptance criteria following repeated worst-case torsional load. 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. Working Length testing and Finger Curved Portion Length testing confirmed that GripTract devices and components meet design tolerances. Finger Maneuver testing confirmed that the Fingers adequately grasp tissue and assist in performing intended procedures such as endoscopic submucosal dissections. A comparison of the endoscope viewing area between the Predicate Device and GripTract Upper GI Model GT-GS100 confirmed that the Proposed Device does not block visualization.

Biocompatibility Testing: GripTract Upper GI Model GT-GS100 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 the Predicate Device. This testing remains valid for GripTract Upper GI Model GT-GS100 and all tests on the Predicate Device confirmed its suitability.

Conclusions

After evaluating GripTract Upper GI Model GT-GS100 for its' 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 Upper GI Model GT-GS100 is as safe and effective as GripTract Lower GI Models when used as indicated to ensure complete positioning of an endoscope and assist with optical visualization, diagnosis, and endoscopic treatment.