October 8, 2019

GI Scientific LLC
% Michele Lucey
President
Lakeshore Medical Device Consulting LLC
128 Blye Hill Landing
Newbury, NH 03255

Re: K183171
Trade/Device Name: ScopeSeal Duodenoscope Protective Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: II
Product Code: ODB, FEI, FDT
Dated: August 8, 2019
Received: August 12, 2019

Dear Michele Lucey:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Martha Betz, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183171

Device Name
ScopeSeal® Duodenoscope Protective Device

Indications for Use *(Describe)*

When properly installed: (i) the ScopeSeal® Duodenoscope Protective Device acts as a protective barrier at the scope's distal end to significantly reduce the level of contamination of the distal end during use and prior to reprocessing, and (ii) the ScopeSeal®'s working channel also provides a protective barrier sealing the duodenoscope's elevator area during use, and (iii) the ScopeSeal® device provides an additional protective benefit after use when kept in place during the ScopeSeal Pre-Cleaning Procedure™ performed after use.

The ScopeSeal® is compatible for use with the Olympus Duodenoscope Model TJF-Q180V.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
ScopeSeal® Duodenoscope Protective Device

Submitter Information:

Submitter's Name:	GI Scientific LLC
Address:	4601 North Fairfax Drive, Suite 1200
	Arlington, VA 22203
Telephone:	508-494-3777
Fax:	866-637-9409
Contact Person:	Michele Lucey
Telephone:	603-748-1374

Date Prepared:	October 1, 2019
Device Trade Name:	ScopeSeal® Duodenoscope Protective Device
Device Classification:	Class II
Classification Name	Endoscope and Accessories
Product Code and CommonName:	ODB, Endoscopic Contamination Prevention Sheath
Subsequent Product Code (s) and Common Name, Regulation Number:	FEI, Instrument, Special Lens, for Endoscope, 876.1500 FDT, Duodenoscope and Accessories, Flexible and Rigid, 876.1500
Predicate Devices:	Sheathing Technologies, Colonoscope/Sigmoidoscope Sheathes (K100966),
Reference Device:	GI Scientific Endoscopic Optical Lens (K140295)

Indications for Use:

When properly installed: (i) the ScopeSeal® Duodenoscope Protective Device acts as a protective barrier at the scope's distal end to significantly reduce the level of contamination of the distal end during use and prior to reprocessing, and (ii) the ScopeSeal®'s working channel also provides a protective barrier sealing the duodenoscope's elevator area during use, and (iii) the ScopeSeal® device provides an additional protective benefit after use when kept in place during the ScopeSeal Pre-Cleaning Procedure™ performed after use.

The ScopeSeal® is compatible for use with the Olympus Duodenoscope Model TJF-Q180V.

Device Description/Technological Characteristics:

The GI Scientific ScopeSeal® Duodenoscope Protective Device is provided as a sterile, single-use device that attaches to the distal end of a duodenoscope. When properly installed the device creates a protective barrier or shield that seals the distal end of the duodenoscope to protect it from contamination during the procedure. The device is designed to preserve the mechanical and optical functionality of the duodenoscope. The ScopeSeal® Duodenoscope Protective Device includes a flexible Working Channel Extension™ that seals against the end of the duodenoscope's working channel, providing a sealed, passageway from the end of the duodenoscope's working channel through the ScopeSeal® device's working channel extension and out to the patient's gastrointestinal tract. This element of ScopeSeal®'s design allows instruments to be passed down the duodenoscope's working channel, through the ScopeSeal® device's Working Channel Extension™, and out to the patient's gastrointestinal tract, without instruments coming into contact with the duodenoscope's elevator, effectively sealing over the elevator area of the duodenoscope. The ScopeSeal® allows passage of device up to 10.7Fr (3.5mm) in diameter.

Performance Data:

Nonclinical performance testing conducted on the ScopeSeal® Duodenoscope Protective Device is provided as follows:

- Seal integrity under simulated use conditions
- Contamination reduction
- Scope compatibility – maintenance of scope function (i.e. irrigation, suction, articulation, device delivery, optics)
- ScopeSeal® delivery and retention

All product performance testing met the acceptance criteria demonstrating that the device has the necessary performance characteristics for its intended use.

Biocompatibility

Categorized as Externally Communicating Device, Tissue Contact, Limited Duration(≤ 24 hours), per ISO 10993-1, the following testing was conducted:

Test Name	Results
Cytotoxicity	Pass - noncytotoxic
Intracutaneous Irritation	Pass - Test requirements for intracutaneous reactivity were met
Sensitization	Pass - did not elicit a sensitization response
Systemic Toxicity	Pass - Test requirements for systemic toxicity were met

No animal or clinical studies were required to demonstrate substantial equivalence.

Substantial Equivalence:

The table below shows how the intended use, device design, principle of operation, and technological characteristics of the ScopeSeal® Duodenoscope Protective Device compared to the predicate device:

Device Comparison Demonstrating Substantial Equivalence			
Feature/ Specification	**ScopeSeal® Duodenoscope Protective Device**	**Sheathing Technologies Colonoscope/ Sigmoidoscope Sheath**	**Comparison to Predicate**
Regulatory Clearance/ Approval Reference	NA	K100966	NA
Product Code	ODB, FEI, FDT	FDF, ODB	Same
21 CFR Regulation Number	876.1500	876.1500	Same
Regulation Name/Common Name	Endoscopic Contamination Prevention Sheath	Endoscopic Contamination Prevention Sheath	Same
Indications for Use	When properly installed: (i) the ScopeSeal® Duodenoscope Protective Device acts as a protective barrier at the scope's distal end to significantly reduce the level of contamination of the distal end during use and prior to reprocessing , and (ii) the ScopeSeal®'s working channel also provides a protective barrier sealing the duodenoscope's elevator area during use, and (iii) the ScopeSeal® device provides an additional protective benefit after use when kept in place during the ScopeSeal Pre-Cleaning Procedure™	Colonoscope/Sigmoidoscope Sheaths are meant for use in non-sterile colonoscopy or sigmoidoscopy procedures to help reduce gross contamination of the endoscope, reducing the exposure of staff to gross contamination during the cleaning procedure.	Intended use is the same, as a sheath or barrier at the distal end of the scope to reduce gross contamination. The ScopeSeal® Statement is more detailed in terms of the additional barrier to the elevator by means of a working channel, and is more specific regarding scope compatibility, and benefits associated with pre-cleaning. These differences do not raise new questions regarding safety and efficacy

Device Comparison Demonstrating Substantial Equivalence			
Feature/ Specification	**ScopeSeal® Duodenoscope Protective Device**	**Sheathing Technologies Colonoscope/ Sigmoidoscope Sheath**	**Comparison to Predicate**
	performed after use. The ScopeSeal® Duodenoscope Protective Device is indicated for use with the Olympus EVIS EXERA II Duodenoscope Model TJF-Q180V.		
Where used (environment)	In a clinical environment	In a clinical environment	Same
Anatomical Sites	Trans oral insertion	Trans anal insertion	Similar. Both devices access the gastrointestinal tract through a natural orifice
Principle of operation	Attaches to the distal end of a duodenoscope/endoscope to provide a sterile disposable barrier while preventing fluid and debris from interfering with visualization. Working channel opening allows instruments to pass through the endoscope to the patient	Covers the scope shaft, open at the proximal and distal end to allow for devices to pass through the endoscope to the patient.	Similar, both devices in some way shield the endoscope while allowing instruments to pass through the endoscope. The Endoscopic lens (reference device) creates an optically clear space to visualize the tissue surface. This difference does not raise new questions of safety and effectiveness for the subject device.
Endoscope Compatibility	Only compatible with the Olympus Duodenoscope Model TJF-Q180V	Various models	Same, compatibility is specified in the labeling
Working channel portal that aligns with the scope working channel	Yes	The distal end is open, does not specifically have an aligned working channel	Same, the open ended Sheathing Technologies device allows for instrument passage but does not contain a working channel portal. This difference does not raise new questions of safety and effectiveness for the subject device.
Compatibility for device passage	Can pass devices up to 3.5mm	The distal end is open, does not specifically have an aligned working channel	Same, device dimensions are designed for scope compatibility.

Device Comparison Demonstrating Substantial Equivalence			
Feature/ Specification	**ScopeSeal® Duodenoscope Protective Device**	**Sheathing Technologies Colonoscope/ Sigmoidoscope Sheath**	**Comparison to Predicate**
Allows for fluid washing of the area over the scope camera and for air to be used to inflate the GI tract	Yes, has a port that allows the scope to still wash the area over the camera and to deliver air to inflate the gastrointestinal tract	Yes, the distal end is open, there is no need for a channel	Same
Optical Element	Includes an optically clear window that covers the duodenoscope's camera and light source, but preserves visualization through its design and optical material	Grips around the distal end of the endoscope, providing a protective covering from the distal end of the scope to the proximal end of the scope, while leaving the optical area of the endoscope uncovered	Same as the Endoscopic Lens Reference Device- all devices are designed to not interfere with visualization
Effect on Endoscope Image	No effect	No effect	Same, all devices are designed not to interfere with visualization
Device Delivery	A Delivery System is provided to enable consistent attachment of the device to the scope	Manually aligned and mounted - no delivery system provided	Same as the Endoscopic Optical Lens Reference Device
Self Retained Attachment	Yes	Yes	Same
Material	Multiple polymers and elastomers	Polyurethane	Similar materials appropriate for their intended use. Difference does not raise new questions of safety and effectiveness
Biocompatibility	Tissue contact materials are biocompatible per ISO 10993	Tissue contact materials are biocompatible per ISO 10993	Same
How Supplied	Sterile single use only	Sterile and nonsterile single use only	Same
Sterilization	Gamma Irradiation	Unknown	Subject device uses a traditional sterilization method. This difference does not raise new questions of safety and effectiveness
Sterility Assurance Level	10^{-6}	Unknown	Consistent with the industry standard for this device type.

Conclusion:

The GI Scientific ScopeSeal® Duodenoscope Protective Device is substantially equivalent to the predicate device and presents no new questions of safety or effectiveness.