August 2, 2019

Lumendi, LLC
John J. Smith, M.D., Ph.D.
Partner
Hogan Lovells U.S. LLP
555 13th Street NW
Washington, DC 20004

Re: K183112
Trade/Device Name: DiLumen Endolumenal Interventional Knife ("DiLumen I_K")
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 3, 2019
Received: July 3, 2019

Dear John Smith:

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,

for
Martha Betz, Ph.D.
Acting Assistant Division 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 on last page

510(k) Number *(if known)*
K183112

Device Name

DiLumen Endolumenal Interventional Knife ("DiLumen I_K™")

Indications for Use *(Describe)*

The DiLumen Endolumenal Interventional Knife ("DiLumen I_K") is a disposable monopolar electrosurgical device intended to be used for marking, cutting, dissecting, and cauterizing tissue within the digestive tract during endoscopic procedures. This device is also indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions under direct endoscopic visualization.

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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510(k) SUMMARY

Lumendi, LLC's DiLumen Endolumenal Interventional Knife (DiLumen I_K™)

Submitter's Information:

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Phone: (203) 463-2669
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Date Prepared: August 1, 2019

Device Identification:

Trade Name: DiLumen Endolumenal Interventional Knife ("DiLumen I_K")

Common Name: Electrosurgical cutting & coagulation device

Classification Regulation: 21 C.F.R. § 878.4400, Electrosurgical cutting and coagulation device and accessories

Product Code: GEI

Device Class: II

Predicate Device: Lumendi DiLumen Endolumenal Interventional Scissors ("DiLumen I_s") (K173405)

Reference Device: Olympus Medical Systems Corporation Single Use Electrosurgical Knife (K171158)

Device Description:

The DiLumen I_K is a sterile, single patient use, disposable electrosurgical instrument. The DiLumen I_K utilizes a pistol style handle, flexible shaft with an articulating section at its distal end, and a stainless-steel knife tip that can be extended and retracted. The handle incorporates controls that allow the clinician to rotate the shaft, extend or retract the knife tip, articulate the distal end of the shaft in a specific plane, and lock the articulation in a fixed position. The DiLumen I_K has a plug at the bottom of the handle that is used to connect the device to an electrosurgical unit. When connected to the generator, and used in combination with grounding pads, high-frequency current can be applied through the knife tip to mark, cut or cauterize tissue at the lesion site. There is also a female luer lock connector on the handle that can be used with a standard luer lock syringe to introduce sterile saline at the distal end for flushing the knife tip or to inject saline into the submucosa to lift lesions.

The DiLumen I_K can also be used in conjunction with other endoscopic devices such as graspers to perform endolumenal interventions.

Intended Use / Indications for Use:

The DiLumen Endolumenal Interventional Knife ("DiLumen I_K") is a disposable monopolar electrosurgical device intended to be used for marking, cutting, dissecting, and cauterizing tissue within the digestive tract during endoscopic procedures. This device is also indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions under direct endoscopic visualization.

Summary of Technological Characteristics:

The technological principle underlying both the subject and predicate devices is monopolar electrosurgical marking, cutting, dissection, and cauterization of tissue. Both devices are based on the following same technological elements:

- Both are sterile, single use, monopolar instruments that allow for one-handed clinician operation.
- Both share key functional characteristics, including the control handle, a flexible shaft with the same diameter, an articulating tip, and stainless-steel end effector.
- Each device can be connected to an electrosurgical generator using a dedicated cable plugged into the handle, in order to make use of monopolar electrical current to facilitate marking, cutting and cauterization.
- Both are prescription-use devices employed by medical professionals in a healthcare facility.

The primary technological difference between the subject and predicate devices is that the proposed device can be used to inject saline into the submucosa, thus forming a bleb that will lift a lesion for enhanced visibility and to allow endoscopic removal. This added feature does not raise different questions of safety or effectiveness, because FDA has cleared other endoscopic devices that have the same functionality such as the reference device, Olympus Medical Systems Corporation's Single Use Electrosurgical Knife (K171158).

The two devices also have slightly different end effector designs and associated operation, but this difference does not raise different questions of safety or effectiveness as both have the same fundamental mechanism of action, and the previously cleared predicate can serve as a knife when used with the blades closed. In addition, the cleared reference device has a very similar end effector design as the DiLumen I_K.

The table below compares the key features of the subject device to the predicate and reference devices.

	Lumendi DiLumen Endolumenal Interventional Knife (I_K)	**Lumendi DiLumen Endolumenal Interventional Scissor (I_s)**	**Olympus Single Use Electrosurgical Knife**
	Subject Device	Predicate Device	Reference Device
510(k)	TBD	K173405	K171158
Intended Use / Indications	The DiLumen Endolumenal Interventional Knife ("DiLumen I_K™") is a	The DiLumen Endolumenal Interventional Scissors ("DiLumen I_s") is a	These instruments have been designed to be used with Olympus endoscopes

	Lumendi DiLumen Endolumenal Interventional Knife (I_K)	**Lumendi DiLumen Endolumenal Interventional Scissor (I_s)**	**Olympus Single Use Electrosurgical Knife**
for Use	disposable monopolar electrosurgical device intended to be used for marking, cutting, dissecting, and cauterizing tissue within the digestive tract during endoscopic procedures. The device is also indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions under direct endoscopic visualization.	disposable monopolar electrosurgical device intended to be used for cutting, dissecting, and cauterizing tissue within the digestive tract during endoscopic procedures.	and electrosurgical units to cut tissue within the digestive tract using high-frequency current. These instruments are indicated for the induction of sterile normal saline into the submucosa to lift lesions using direct visualization through an endoscope.
Sterility	Sterile – EO	Sterile – EO	Sterile – EO
Shelf Life	One year	One year	Unknown
Single use/reusable	Single Use, fully disposable	Single Use, fully disposable	Single Use, fully disposable
Basic Design	Proximal handle with controls, flexible shaft, articulating section, retractable / extendable knife tip; Flush tube inside shaft	Proximal handle with controls, flexible insulated shaft, articulating section and rotating scissor tip	Proximal handle with controls, flexible shaft, retractable / extendable knife tip; Flush tube inside shaft
Patient-Contacting Materials	Stainless steel (knife tip), medical-grade polymers	Stainless steel (blades), medical-grade polymers	Stainless steel (knife tip), medical-grade polymers
End Effector	Shaft with ball tip (knob-shape)	Scissor Blades	Shaft with ball tip (knob-shape)
Electrical connector	Banana plug at bottom of handle	Banana plug at bottom of handle	Banana plug in handle
Type of working channel	Channel external to endoscope	Channel external to endoscope	Endoscope's working channel
Compatible diameter of channel	6 mm	6 mm	2.8 mm to 6.0 mm
Shaft length	95 cm, 140 cm	95 cm, 140 cm	195 cm, 230 cm
Syringe port	Luer lock in handle	None	Luer lock in handle

Performance Data:

Performance testing has demonstrated that the DiLumen I_K meets specifications and is as safe and effective as the predicate device. The following non-clinical performance data were provided in support of this 510(k) notice:

1. Biocompatibility (cytotoxicity, sensitization, irritation, systemic toxicity, material mediated pyrogenicity)
2. End Effector Articulation Test
3. Leakage Test

4. Bleb Formation Test
5. Internal Pressurization Test
6. Shaft and Handle Rotation Accuracy Test
7. Electrical Continuity Test
8. Electrical Safety Test
9. Electromagnetic Compatibility Test
10. Packaging and Transit Evaluation
11. Design Validation
12. Human Factors/Usability Testing

In all instances, the device functioned as intended and the results observed were as expected.

Conclusion:

The DiLumen I_K device has the same intended use and similar indications, technological characteristics, and principles of operation as the identified predicate and reference devices. The minor differences in end effector and saline flush capabilities between the DiLumen I_K and its predicate device do not raise any new questions of safety of effectiveness, and the performance data presented in the 510(k) notice further support that the DiLumen I_K functions as safely and performs as well as the identified predicate. Thus, the DiLumen I_K is substantially equivalent to the predicate Lumendi DiLumen Endolumenal Interventional Scissors ("DiLumen I_S") (K173405).