May 22, 2018

Lumendi, LLC
% John J. Smith, MD, JD
Partner
Hogan Lovells U.S. LLP
555 13th Street NW
Washington, DC 20004

Re: K173405
Trade/Device Name: DiLumen Endolumenal Interventional Scissors ("DiLumen Is™")
Regulation Number: 21 CFR§ 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Dated: April 6, 2018
Received: April 6, 2018

Dear John J. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173405

Device Name
DiLumen Endolumenal Interventional Scissors ("DiLumen Is™")

Indications for Use *(Describe)*
The DiLumen Endolumenal Interventional Scissors ("DiLumen Is™") is a disposable monopolar electrosurgical device intended to be used for cutting, dissecting, and cauterizing tissue within the digestive tract during endoscopic procedures.

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

Lumendi, LLC's DiLumen Endolumenal Interventional Scissors (DiLumen I_s™)

Submitter's Information:

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Date Prepared: October 31, 2017

Device Identification:

Trade Name: Dilumen Endolumenal Interventional Scissors (DiLumen I_s™)
Common Name: Electrosurgical cutting & coagulation device
Classification Regulation: 21 C.F.R. § 878.4400, Electrosurgical cutting & coagulation device and accessories
Product Code: GEI
Device Class: II

Predicate Device: Cambridge Endoscopic Devices, Inc. pureWrist™ electrocautery laparoscopic instruments (K061425)

Reference Device: Sumitomo Bakelite Co., Ltd. SB Knife (K152771)

Device Description:

The DiLumen I_s is a sterile, single patient use, disposable instrument that consists of a pistol style handle, a flexible shaft with an articulating section at the distal end, and scissor blades. The handle incorporates controls that enable one-handed operation of the device, including rotating the shaft; opening, closing and rotating the blades independently from the shaft; articulating the distal end of the shaft in a specific plane; and locking the articulation in a fixed position. This allows the clinician maximum flexibility to cut, dissect and cauterize tissue during endoscopic interventions in the digestive tract. The clinician can insert the DiLumen I_s into any endoscopic tool channel with a diameter of at least 6mm. With the DiLumen I_s under direct visualization, the clinician can position the scissor blades as appropriate for the particular procedure using blade rotation, blade articulation, and shaft rotation as necessary. The clinician can then cut gastrointestinal tissue either with or without energizing the blades, depending on the specific need during the procedure.

In addition, the DiLumen I_s has a plug at the bottom of the handle. If desired by the clinician, this plug can be used to connect the device to an electrosurgical generator via a dedicated cord in order

to apply monopolar electrical current through the blades to the target site in the gastrointestinal tract. When the device is connected to the generator, monopolar current can be applied through the blades to cut or cauterize tissue electrosurgically.

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

Intended Use / Indications for Use:

The DiLumen Endolumenal Interventional Scissors ("DiLumen I_s") is a disposable monopolar electrosurgical device intended to be used for cutting, dissecting, and cauterizing tissue within the digestive tract during endoscopic procedures.

Summary of Technological Characteristics:

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

- Both are sterile, single use, monopolar scissors that allow for one-handed clinician operation.
- Both share key functional characteristics, including the control handle, an insulated working shaft with the same diameter, an articulating tip, and two curved rotating stainless-steel blades.
- 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 or enhance the scissors' functioning.
- 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 predicate's working shaft is rigid and shorter than that of the DiLumen Is. This does not raise different questions of safety or effectiveness, because the greater flexibility and length of the DiLumen I_s working shaft simply makes it easier for the device to follow the path inside a flexible tool channel within the gastrointestinal tract; it does not alter the device's principles of operation or the purposes for which it is used. Furthermore, FDA has cleared other endoscopic cutting devices with longer flexible shafts, such as the reference device, Sumitomo Bakelite's SB Knife (K152771). The DiLumen I_s also has one feature that is not found in the predicate: a tethered Blades Lock attached to the bottom of the handle that can be inserted between the trigger and the body of the handle to keep the trigger squeezed and the blades closed. However, this addition is for user convenience; the predicate's blades could also be kept closed by the clinician.

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

	Lumendi DiLumen Endolumenal Interventional Scissors (I_s)	**Cambridge Endoscopic Devices, Inc. pureWrist™ electrocautery laparoscopic Instruments**
510(k)	TBD	K061425
Intended Use / Indications for Use	The DiLumen Endolumenal Interventional Scissors ("DiLumen I_s") is a disposable monopolar electrosurgical device intended to be used for cutting, dissecting, and	The pureWrist™ electrocautery laparoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of

	Lumendi DiLumen Endolumenal Interventional Scissors (I_s)	Cambridge Endoscopic Devices, Inc. pureWrist™ electrocautery laparoscopic Instruments
	cauterizing tissue within the digestive tract during endoscopic procedures.	tissue.
Sterility	Sterile – EO	Sterile – Radiation
Shelf Life	One year	Two years
Single use/reusable	Single Use, fully disposable	Single Use, fully disposable
Basic Design	Proximal handle with controls, flexible insulated shaft, articulating section and rotating scissor tip	Proximal handle with controls, rigid insulated shaft, articulating section and rotating scissor tip
Patient-Contacting Materials	Stainless steel (jaws), medical-grade polymers: Pebax with embedded Aramid braid (flexible shaft), Fluoropolymer (Articulation sleeve)	Stainless steel (jaws); FEP, PEEK, Pebax, Tecoflex, Cyanoacrylate, PET
Electrical connector	Banana plug at bottom of handle	Banana plug at bottom of handle
Cautery Type	Monopolar cautery	Monopolar cautery
Shaft Outer diameter	5 mm	5 mm
Shaft length	95 cm, 140 cm	15 - 45 cm
Operating principle	The DiLumen I_s are operated manually using one hand to control blade position and blade actuation. The end effector can be rotated, articulated and positioned, allowing the scissor blades to cut, dissect, and cauterize tissue either with or without monopolar energy.	The pureWrist™ electrocautery laparoscopic Instruments are operated manually using one hand to control blade position and blade actuation. The end effector can be rotated, articulated and positioned, allowing the scissor blades to cut, dissect, and cauterize tissue with or without monopolar energy.

Performance Data:

Performance testing has demonstrated that the DiLumen I_s meets specifications and is as safe and effective as the predicate. The following performance data were provided in support of this Premarket Notification:

1. Biocompatibility (cytotoxicity, sensitization, irritation, systemic toxicity, material mediated pyrogenicity)
2. Dissection Force Test
3. Tip Articulation Accuracy Test
4. Tip Rotation Accuracy Test
5. Shaft Rotation Accuracy Test
6. Cutting Durability Test
7. Monopolar Cable Insertion and Removal Force Test
8. Electrical Safety Test
9. Electromagnetic Compatibility Test
10. Usability Evaluation
11. Packaging and Transit Test
12. User Validation
13. EO Residuals

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

Conclusion:

The DiLumen I_s device has the same intended use and similar indications, technological

characteristics, and principles of operation as the identified predicate. The minor technological differences between the DiLumen I_S and its predicate device do not raise any new questions of safety of effectiveness. Furthermore, the performance data presented in the 510(k) notice further support that the DiLumen I_S functions as safely and performs as well as the identified predicate. Thus, the DiLumen I_S is substantially equivalent to the predicate pureWrist™ electrocautery laparoscopic instruments (K061425).