October 30, 2018

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

Re: K182540
Trade/Device Name: DiLumen Endolumenal Interventional Platform
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: September 14, 2018
Received: September 14, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

FDA Jeffrey W. Cooper -S
2018.10.30 15:07:39
-04'00'

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)*
K182540

Device Name

DiLumen Endolumenal Interventional Platform

Indications for Use *(Describe)*

The Lumendi DiLumen is an accessory to an endoscope. The DiLumen dual balloon accessory is intended for use with any standard endoscope that has a distal tip outer diameter of 12.5 – 14.3 mm. The device is indicated to ensure complete positioning of an endoscope during navigation in the large intestine, while assisting with optical visualization, diagnosis, tissue manipulation, and endoscopic treatment.

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 Platform

Submitter's Information:

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Contact Person:

Dennis J. Daniels
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Email: Dennis.Daniels@Lumendi.com

Date Prepared: September 14, 2018

Device Identification:

Trade Name: DiLumen Endolumenal Interventional Platform

Common Name: Endoscope Accessory

Device Class: II

Device Panel: Gastroenterology/Urology

Classification Regulation / Product Code: 21 C.F.R. § 876.1500 Endoscope and Accessories; FDF

Predicate/Reference Devices:

- ORISE Tissue Retractor System (K173400) (predicate device)
- DiLumen Endolumenal Interventional Platform (K162428) (reference device)

Intended Use / Indications for Use:

The Lumendi DiLumen is an accessory to an endoscope. The DiLumen dual balloon accessory is intended for use with any standard endoscope that has a distal tip outer diameter of 12.5 – 14.3 mm. The device is indicated to ensure complete positioning of an endoscope during navigation in the large intestine, while assisting with optical visualization, diagnosis, tissue manipulation, and endoscopic treatment.

Device Description:

The DiLumen Endolumenal Interventional Platform is a non-sterile, single-use, close-fitting sleeve that fits securely over a standard endoscope.

The DiLumen utilizes two balloons to position and stabilize the endoscope within a patient's large intestine. After the DiLumen is installed over the endoscope, the endoscope and DiLumen are navigated to the target zone with the balloons deflated. At the area of interest, the Aft Balloon, which is attached to the DiLumen sleeve, is inflated until it contacts the intestinal wall near the proximal end of the articulating section of an endoscope. The second balloon, the Fore Balloon, is

also attached to the sleeve via two flexible extension push rods and is deployed at the distal end of the endoscope at a variable distance. Once extended and inflated, the Fore Balloon contacts the patient's intestinal wall, and in combination with the Aft Balloon, creates an isolated diagnostic or therapeutic zone. Both balloons are controlled using an Inflation Handle with a squeeze bulb to manually inflate and deflate them (independently) with ambient air as they assist in stabilizing the endoscope and the therapeutic area.

This 510(k) notice encompasses a minor revision to the device's indications statement to specify that it can be used for tissue manipulation, as well as addition of suture loops to the Fore Balloon skirt to facilitate that functionality. The DiLumen is designed to permit the usage of any standard endoscopic tool through the endoscope working channel. The endoscope flexibility, maneuverability and functionalities (such as visualization, suction, insufflations, etc.) are unaffected by the presence of the DiLumen, including the sleeve, balloons, and suture loops.

Substantial Equivalence:

The subject and predicate devices are both intended to physically manipulate/retract tissue as needed in order to facilitate visualization and diagnosis/treatment in the gastrointestinal tract. The minor differences in the subject device's indications either represent a narrower use as compared to the predicate (*e.g.,* reference to the large intestine as opposed to the gastrointestinal tract) or have been previously cleared in the prior version of the DiLumen (K162428, reference device), and do not alter the device's diagnostic/therapeutic effects. Both devices are intended for single use only.

The DiLumen design is similar to that of the ORISE™ System. While the predicate deploys retractor arms rather than using push rods to extend balloons, the two mechanisms both create a more stable platform in the GI tract and facilitate visualization. The devices also operate similarly to achieve tissue manipulation/retraction. Both tools allow the creation of an isolated therapeutic zone, or working chamber, within which tissue can be better visualized, maneuvered, retracted, or dissected in support of endolumenal procedures. Moreover, the subject device's design is nearly identical to that of the reference device which FDA has already reviewed and cleared, with minor design modifications as compared to the prior version performed under design controls and either verified through bench testing or supported by a rationale that additional testing was not required.

Performance Data:

Because the subject DiLumen is essentially identical in design to the previously cleared DiLumen Endolumenal Interventional Platform, the testing submitted in that 510(k) notice is relied upon to establish the device's biocompatibility and functional and mechanical performance. In addition, the company has conducted bench testing to assess the performance and impact of the suture loops added to the Fore Balloon.

Conclusion:

In sum, the subject device has the same intended use and similar indications for use, technological characteristics, and principles of operation to the predicate device. The minor differences between the devices do not raise different types of safety or effectiveness questions, and are further supported by the subject device's being nearly identical in design and indications to the reference device (the previously cleared DiLumen). Moreover, the data presented/referenced in this submission support that the subject device performs to its pre-defined specifications and is at least as safe and effective as the predicate and reference devices. As such, the subject DiLumen Endolumenal Interventional Platform can be found substantially equivalent.