April 21, 2021

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

Re: K210851
Trade/Device Name: DiLumen Endolumenal Interventional Platform ("DiLumen")
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDF
Dated: March 22, 2021
Received: March 22, 2021

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210851

Device Name

DiLumen Endolumenal Interventional Platform ("DiLumen")

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's DiLumen Endolumenal Interventional Platform.

Submitter's Information:

LUMENDI, LLC
253 Post Road West
Westport, CT 06880
Phone: (203) 463-2669
Fax: (203) 557-0459

Contact Person:

Dennis J. Daniels
Senior Director, Regulatory Affairs and Quality Assurance
Telephone: (203) 557-6335
Fax: (203) 557-0459
Email: Dennis.Daniels@Lumendi.com

Date Prepared: March 22, 2021

Device Identification:

Trade Name:	DiLumen Endolumenal Interventional Platform ("DiLumen")
Common Name:	Endoscope and Accessories
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology
Regulation / Product Code:	21 C.F.R. § 876.1500; FDF

Predicate Device:

- Lumendi, LLC's DiLumen Endolumenal Interventional Platform (K182540)

Purpose of the Special 510(k) Notice:

The subject device incorporates minor technological modifications to the DiLumen cleared under K182540; the indications for use remain the same.

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.

This intended use / indications for use statement is identical to that of the predicate device.

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 tissue 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 intestine tissue, and in combination with the Aft Balloon, creates an isolated diagnostic / 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. The Suture Loops attached to the Fore Balloon of the DiLumen allow clinicians to manipulate tissue when used with an endoscopic clip.

The endoscope flexibility, maneuverability and functionalities (such as visualization, suction, insufflation, etc.) are unaffected by the presence of the DiLumen. The DiLumen is designed to permit the usage of any standard tool through the endoscope working channel.

Technological Characteristics / Substantial Equivalence:

The subject device is identical to the predicate device with the exception of three minor modifications:

1. The main lumen of the DiLumen Sleeve now has a hydrophilic coating to provide lubricity without using additional lubricants;
2. A Flush Port has been added to the DiLumen Base Handle so that sterile water or saline can – at the clinician's discretion – be introduced into the Sleeve to clear debris that may collect inside it, as well as to hydrate the hydrophilic coating; and
3. The Suture Loops on the DiLumen Fore Balloon are now made from 2-0 monofilament nylon suture rather than 2-0 monofilament polypropylene suture, and the loops are now supplied in two different colors and sizes (diameters).

These added and/or modified components were initiated primarily as user conveniences to make the DiLumen easier to use and do not change the device's intended use, principles of operation, or ability to meet performance specifications as previously cleared by FDA. As such, they do not raise different questions of safety or effectiveness.

Performance Data:

Because the subject DiLumen is nearly identical in design to the previously cleared DiLumen Endolumenal Interventional Platform (K182540), the bench testing to support this 510(k) notice is limited to the device's biocompatibility, functional and mechanical performance, which are parameters that could theoretically (but were confirmed not to be) affected by the changes. The following evaluations and tests were performed on the subject (modified) DiLumen:

- Design Verification and Validation; including pull force and push force testing;
- Clinical User Validation Testing;
- Biocompatibility testing per ISO 10993-1:2009, 10993-5, 10993-7, 10993-10, 10993-11 and USP 42-NF37:2019, <151>.

Conclusion:

In sum, the subject device has the same intended use and indications for use as well as the same principles of operation, and very similar technological characteristics, as the predicate device. The minor material and component differences between the devices do not raise different types of safety or effectiveness questions. Moreover, the data presented and referenced in this submission support that the subject device performs to its pre-defined specifications and is as safe and effective as the predicate. As such, the subject DiLumen Endolumenal Interventional Platform can be found substantially equivalent.