DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 6, 2016

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

Re: K162428
Trade/Device Name: DiLumen Endolumenal Interventional Platform
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FDF
Dated: October 24, 2016
Received: October 24, 2016

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*
K162428

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 and a working length of 1680 mm or greater. The device is indicated to ensure complete positioning of an endoscope in the large intestine, and assist with optical visualization, diagnosis, 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

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

Date Prepared: August 30, 2016

Device Identification:

Trade Name: DiLumen Endolumenal Interventional Platform
Common Name: Endoscope Accessory
Device Class: II
Device Panel: Gastroenterology/Urology

Classification:

21 C.F.R. § 876.1500 (Endoscope and accessories)
Product Code: FDF

Predicate/Reference Devices:

- Fujinon EC-450B15 Double Balloon Enteroscopy System (K090116)
- Smart Medical Systems NaviAID™ BGE (K060923) (reference device)
- Smart Medical Systems NaviAID™ BGC (K102616) (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 and a working length of 1680 mm or greater. The device is indicated to ensure complete positioning of an endoscope in the large intestine, and assist with optical visualization, diagnosis, and endoscopic treatment.

Device Description/Technological Characteristics:

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. Once the clinician is at the area of interest, the Aft Balloon, which is attached to the DiLumen sleeve, will be 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 the two balloons with ambient air. The balloons assist in stabilizing the endoscope and the therapeutic area and are inflated or deflated independently.

The balloons and sleeve are designed to permit the usage of any standard endoscopic tool (such as biopsy forceps, snare, needle, etc.) 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.

Substantial Equivalence:

The DiLumen device has the same intended use and similar indications and technological characteristics as the Fujinon EC-450B15 system (K090116) and Smart Medical Systems' NaviAID™ BGE (K060923) and NaviAID™ BGC (K102616) devices.

The subject device and the Fujinon predicate consist of the same basic components to ensure complete positioning of the endoscope – specialized balloons, an over-tube/sleeve, and an inflation system; the NaviAid reference devices do not have a sleeve but include a balloon(s) and inflation/extension tube. While the DiLumen is not used to advance the endoscope to the target location like the Fujinon predicate, it shares key functional characteristics including balloon inflation pressure, extension of a balloon from the endoscope distal tip at a variable distance, and use of the balloons to stabilize the endoscope. The balloon diameter is also the same in the DiLumen and the NaviAID™ BGC; the balloons in the NaviAid™ BGE and Fujinon predicate are slightly smaller to accommodate use in the small intestine.

The DiLumen and its predicate and reference devices are prescription-use devices used by medical professionals in a healthcare facility. Each device is intended for single use only and should not be re-used. Performance testing has demonstrated that the DiLumen meets specifications and is as safe and effective as the cited predicates.

In sum, the minor technological differences between the DiLumen and its predicate and reference devices do not raise different types of safety or efficacy questions; as such, the DiLumen can be found substantially equivalent.

Performance Data:

The following performance data were provided in support of this Premarket Notification:

1. Biocompatibility (cytotoxicity, sensitization, irritation, and systemic toxicity)
2. Balloon Burst Pressure Test
3. Balloon Diameter, Inflation/Deflation and Leakage Test

4. Relief Valve Test
5. Device Slip Relative to Scope Test
6. Sleeve Buckling Test
7. Fore Balloon Extension Test
8. Colon Grip Test
9. Articulation Test
10. Sleeve Leak Test
11. Therapeutic Zone Creation Test
12. Fatigue/Cycling Test
13. Extension Position Locking Test
14. Flexibility Test
15. Force/Bond Test
16. Insertion Force Test
17. Packaging and Transit Test
18. User Validation

Conclusion:

From the data presented it is concluded that the subject device is substantially equivalent to the predicates based on intended use/indications for use and technological characteristics. The minor technological differences between the DiLumen and its predicate devices raise no new issues of safety or effectiveness. Bench testing data demonstrate that the DiLumen has substantially equivalent performance to the predicates.