April 17, 2018

Lumendi, LLC
% John J. Smith, MD, JD
Partner
Hogan Lovells U.S. LLP
553 13th Street NW
Washington, DC 20004

Re: K173317
Trade/Device Name: DiLumen C2; DiLumen Tool Mount
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: March 6, 2018
Received: March 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,

Benjamin R. Fisher -S

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)*
K173317

Device Name
DiLumen C2; DiLumen Tool Mount

Indications for Use *(Describe)*
The Lumendi DiLumen C2 is an endoscope accessory intended 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.

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510(k) SUMMARY
Lumendi, LLC's DiLumen C^2 and Tool Mount

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: April 5, 2018

Device Identification:

Trade Name: DiLumen C^2 and Tool Mount

Common Name: Endoscope Accessory

Classification Regulation: 21 C.F.R. § 876.1500 (Endoscope and accessories)

Product Codes: FDF

Device Class: II

Predicate Device: DiLumen Endolumenal Interventional Platform (K162428)

Reference Device: FISSO Holding System (K070509)

Device Description:

The DiLumen C^2 consists of a sleeve including two inflatable balloons that fits over a standard endoscope to facilitate positioning and stabilization of the endoscope during surgical procedures. The C^2 comes into limited (<24 hour) contact with breached or compromised surfaces of the patient. The C^2 is provided sterile and intended only for single patient use.

To stabilize the system during clinical use, the C^2 is provided with its own designated accessory, known as the Tool Mount, a metal holding system that fastens the tool channels to a surgical table rail. The Tool Mount is re-usable and is provided non-sterile; it must be cleaned and sterilized prior to each use following the instructions in the device labeling.

Intended Use / Indications for Use:

> *The Lumendi DiLumen C^2 is an endoscope accessory intended to ensure complete positioning of an endoscope in the large intestine, and assist with optical visualization, diagnosis, and endoscopic treatment.*

The identified predicate device for the DiLumen C^2 has similar indications for use as the subject device. Like the predicate Lumendi DiLumen (K162428), the DiLumen C^2 device is intended for use as an accessory to an endoscope to position/stabilize the endoscope and assist in optical visualization, diagnosis, and endoscopic treatment in the large intestine. Accordingly, the differences in indications for use between the DiLumen C^2 and its predicate device are not critical to the intended therapeutic/diagnostic use of the device and do not affect its safety or effectiveness when used as labelled.

Technological Characteristics and Principles of Operation:

The DiLumen C^2 Endolumenal Interventional Platform is a sterile, single-use, close-fitting sleeve that fits securely over a standard endoscope.

The DiLumen C^2 utilizes two balloons to position and stabilize the endoscope within a patient's large intestine. After the DiLumen C^2 is installed over the endoscope, a collet is secured to the endoscope distal tip. 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 C^2 sleeve, will be inflated until it contacts the intestinal wall near the proximal end of the articulating section of the 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 independently 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.

The flexibility, maneuverability and functionalities (such as visualization, suction, insufflations, etc.) of the endoscope are unaffected by the presence of the DiLumen C^2. The DiLumen C^2 has two 6-mm diameter tool channels. The tool channels are located 180° apart at the distal end of the sleeve. The tool channels provide the clinician access at the therapeutic site so that the clinician can use flexible endoscopic tools such as graspers, scissors, knives, etc. to perform endolumenal interventions.

The DiLumen C^2 is provided with a designated accessory, the Tool Mount, which holds the tool channels in a fixed position to facilitate their use. The Tool Mount consists of the previously cleared FISSO Holding System (K070509) articulating arm with an added permanently attached tool bar to firmly hold the C^2 tool channels in the clinician's preferred orientation. The tool bar has flanges that firmly hold the proximal ends of the DiLumen C^2 tool channels and are adjustable in three angular positions. The Tool Mount and holding system is attached to a standard surgical table rail using a rail clamp. The Tool Mount has similar indications for use and function as the FISSO Holding System reference device, namely to hold endoscopes, equipment, and patient positioning accessories during diagnostic and therapeutic procedures, but because the Tool Mount is designed for use with only the DiLumen C^2, its intended use is narrower.

Performance Data:

Performance testing has demonstrated that the DiLumen C^2 meets specifications and is as safe and effective as the predicate. As the DiLumen C^2 shares many of the same components as the predicate devices, bench testing primarily targeted verification of the balloon integrity and operation of the DiLumen C^2 with an endoscope and with the Tool Mount. The following performance data were provided in support of this Premarket Notification:

1. Biocompatibility (cytotoxicity, sensitization, irritation, systemic toxicity, material mediated pyrogenicity)
2. Balloon Diameter, Inflation/Deflation and Leakage Test
3. Device Slip Relative to Scope Test
4. Fore Balloon Extension Test
5. Articulation Test
6. Colon Grip Test
7. Therapeutic Zone Creation Test
8. Tuohy Leak Force / Bond Leak Test
9. Insertion Force Test
10. Packaging and Transit Test
11. User Validation
12. EO residuals
13. Tool Mount Cleaning and Sterilization Validation
14. Tool Mount Positioning and Locking Test
15. Tool Mount Validation

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

No animal or clinical testing was required to demonstrate substantial equivalence to the predicate.

Substantial Equivalence:

The subject DiLumen C^2 device has nearly identical technological characteristics as the DiLumen Endolumenal Interventional Platform cleared under K162428, with the main differences between the devices being:

1. The subject device has two tool channels;
2. The subject device has a dedicated Tool Mount accessory;
3. The subject device is secured to the endoscope distal tip using a collet;
4. The internal diameter of the DiLumen C^2's balloons is slightly larger; and
5. The subject device is EO-sterilized.

Because the DiLumen C^2 and the predicate consist of many of the same components to ensure complete positioning of the endoscope and advance the endoscope to the target location in the same manner, and as further demonstrated by performance testing, these minor technological differences do not raise different types of safety or efficacy questions. In addition, the Tool Mount accessory – which is limited to use with the C^2 device – is very similar to the FISSO Holding System reference device (K070509).

A table comparing the key features of the subject and predicate devices is provided below.

	Lumendi DiLumen C^2	**Lumendi DiLumen Endolumenal Interventional Platform**
510(k)	TBD	K162428
Intended Use / Indications for Use	The Lumendi DiLumen C^2 is an endoscope accessory intended to ensure complete positioning of an endoscope in the large intestine, and assist with optical	The Lumendi DiLumen is an accessory to an endoscope. The DiLumen dual balloon accessory is intended for use with any endoscope that has an outer diameter of 12.5 – 14.3 mm and a minimum working length of 1680

	Lumendi DiLumen C^2	**Lumendi DiLumen Endolumenal Interventional Platform**
	visualization, diagnosis, and endoscopic treatment.	mm. The device is indicated to ensure complete positioning of an endoscope in the large intestine, and assist with optical visualization, diagnosis, and endoscopic treatment.
Sterility	Sterile - EO	Non-sterile
Single use/reusable	Single Use	Single Use
Balloon	Low durometer Polyurethane	Low durometer Polyurethane
Sleeve	Pellethane with 2.5% Glycolube translucent	Pellethane with 2.5% Glycolube translucent
Inflation tube/ Pushrod Assembly	Isoplast Pebax Pellethane	Isoplast Pebax Pellethane
Collet	Lexan	NA
Tool Channel Tubing	FEP; Pellethane; stainless steel internal braid;	NA
Tool Channel Components	Polyurethane; Pellethane with 2.5% Glycolube ;ePTFE Lexan; silicone;	NA
Compatible Endoscope Tip Diameter	11.5 - 14.5 mm	12.5 - 14.3 mm
Fore/Aft Balloons – Inner Diameter	28.5 mm	21.5 mm
Fore/Aft Balloons – Outer Diameter	60 mm	60 mm
Balloon Pressure	45 ± 12 mmHg	45 ± 12 mmHg
Relief Pressure	55 mmHg	55 mmHg
Working Length	1680 mm	1680 mm
Inflation Source	Manual inflation bulb	Manual inflation bulb
Shelf Life	12 months	12 months
Accessories	The Lumendi DiLumen C^2 has a designated Tool Mount that is intended to mount to a surgical table rail and hold the DiLumen C^2 tool channels during endoscopic treatment. The Tool Mount is made of stainless steel and is supplied non-sterile.	The Lumendi DiLumen can be used with various additional endoscope accessories, but is not supplied with any designated accessories.

Conclusion:

The DiLumen C^2 is as safe and effective as the DiLumen Endolumenal Interventional Platform cleared under K162428. The device has the same intended use and principles of operation, and similar indications for use and technological characteristics, as the predicate device, and its designated accessory (the Tool Mount) has similar indications and function as the identified reference device (the FISSO Holding System cleared under K070509). The minor differences in indications and technology do not alter the intended therapeutic use of the device and do not raise any new questions of safety or effectiveness when the device is used as labelled. In addition, bench testing data demonstrate that the DiLumen C^2 is as safe and effective as the predicate device. Thus, the DiLumen C^2 is substantially equivalent to the DiLumen Endolumenal Interventional Platform.