October 22, 2021

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

Re: K211819
Trade/Device Name: DiLumen C2 and Tool Mount
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDF
Dated: September 17, 2021
Received: September 17, 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 and Part 809 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: 06/23/2023
See PRA Statement below

510(k) Number *(if known)*
K211819

Device Name

DiLumen C^2 and Tool Mount

Indications for Use *(Describe)*

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.

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)

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

Submitter's Information:

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Date Prepared: June 11, 2021

Device Identification:

Trade Name:	DiLumen C^2 and Tool Mount
Common Name:	Endoscope Accessory
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology
Regulation / Product Code:	21 C.F.R. § 876.1500; FDF

Predicate/Reference Devices:

- Lumendi, LLC's DiLumen C^2 (K173317) (predicate device)
- Lumendi, LLC's DiLumen Endolumenal Interventional Platform (K210851) (reference device)

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.

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 is provided non-sterile and does not require disinfection or sterilization prior to use. The device is 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, disinfected and sterilized prior to each use following the instructions in the device labeling.

Technical Characteristics / Substantial Equivalence:

The subject device is identical to the predicate device except for minor technological differences. These include provision of the device in two shorter lengths, instead of the original 168 cm length; addition and removal of certain secondary components to further facilitate use of the device by clinicians without altering the clinical workflow; modifying certain dimensions and features of other components (again, without altering how the device is used); the endoscope insertion tube seal type; lengthening the Tool Flange to accommodate changes in a 510(k)-exempt accessory used with the device; and adding a hydrophilic coating to the inner lumen of the Sleeve. None of the changes alter the device's intended use/indications for use, principles of operation, or ability to meet key performance specifications as previously cleared by FDA. As such, they do not raise different questions of safety or effectiveness.

	Subject Device: Lumendi DiLumen C^2 and Tool Mount	**Predicate Device : Lumendi DiLumen C^2 and Tool Mount (K173317)**	**Reference Device : Lumendi DiLumen Endolumenal Interventional Platform (K210851)**
Classification	21 C.F.R. 876.1500, Product Code FDF		
Common Name	Endoscope Accessory		
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 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 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 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	Non-sterile	Sterile EO	Non-sterile
Single use/reusable	Single Use	Single Use	Single Use
Balloons	Low durometer Polyurethane	Low durometer Polyurethane	Low durometer Polyurethane
Sleeve	Extruded polyurethane with main lumen having a hydrophilic coating.	Extruded polyurethane	Extruded polyurethane with main lumen having a hydrophilic coating.
Tool Channel Tubing	FEP; Pellethane; stainless steel internal coil	FEP; Pellethane; stainless steel internal coil	NA
Fore and Aft Balloon Outer Diameter	60 mm	60 mm	60 mm
Fore Balloon Inner Diameter	17.6 mm	28.5 mm	17.6 mm
Balloon Pressure	45 ± 12 mmHg	45 ± 12 mmHg	45 ± 12 mmHg
Relief Pressure	55 mmHg	55 mmHg	55 mmHg
Working Length	130 cm and 103 cm	168 cm	130 cm and 103 cm

	Subject Device: Lumendi DiLumen C^2 and Tool Mount	**Predicate Device : Lumendi DiLumen C^2 and Tool Mount (K173317)**	**Reference Device : Lumendi DiLumen Endolumenal Interventional Platform (K210851)**
Inflation Source	Manual inflation bulb	Manual inflation bulb	Manual inflation bulb
Shelf Life	24 months	12 months	24 months
Accessories	A designated Tool Mount (DiLumen Tool Mount model D-4000) 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 provided non-sterile.		Can be used with various additional endoscope accessories but is not supplied with any designated accessories.

Performance Data:

Performance testing has demonstrated that the DiLumen C^2 meets specifications and is as safe and effective as the predicate device. As the DiLumen C^2 shares many of the same components as the predicate and reference devices, bench testing primarily targeted verification of the balloon integrity and operation of the DiLumen C^2 with an endoscope. The following performance data were provided in support of this 510(k) notice:

1. Biocompatibility (cytotoxicity, sensitization, irritation, systemic toxicity, material mediated pyrogenicity)
2. Fore and Aft Balloon Diameter
3. Therapeutic Zone Creation
4. Balloon/Endoscope Centering
5. Endoscope Insertion Force
6. Instrument Insertion and Removal Force
7. Tool Channel Deflection
8. User Verification Testing

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

Conclusion:

In sum, the subject device has the same intended use/indications for use and principles of operation, and very similar technological characteristics, as 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 similarities in technology to the reference device. 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 C^2 and Tool Mount can be found substantially equivalent to the predicate DiLumen C^2 and Tool Mount.