February 10, 2023

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

Re: K221452
Trade/Device Name: DiLumen C1, EZ1 and Tool Mount
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF
Dated: January 11, 2023
Received: January 11, 2023

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,

Sivakami Venkatachalam -S

for
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)*
K221452

Device Name

DiLumen C1, EZ1 and Tool Mount

Indications for Use *(Describe)*

The Lumendi DiLumen C1 and EZ1 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 C1, EZ1 and Tool Mount – K221452

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: January 24, 2023

Device Identification:

Trade Name:	DiLumen C1, EZ1 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
Classification Name:	Endoscope and Accessories

Predicate/Reference Devices:

- Lumendi, LLC's DiLumen C2 (K211819) (predicate device)

Intended Use / Indications for Use:

The Lumendi DiLumen C1and EZ1 devices are 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 C1 and EZ1 consists of a sleeve with an inflatable balloon at the distal end that fits over a standard endoscope to facilitate positioning and stabilization of the endoscope during surgical procedures. The DiLumen C1 includes an attached flexible tool channel to allow endoscopic tools to be inserted through it and used in conjunction with the endoscope. The DiLumen EZ1 does not have the tool channel. The C1 and EZ1 are provided non-sterile and do not require disinfection or sterilization prior to use. The devices are intended only for single patient use.

To stabilize the system during clinical use, the C1 is used with its own designated accessory, known as the Tool Mount, a metal holding system that fastens the tool channel 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. As the EZ1 does not have a tool channel, the Tool Mount is not used to perform its intended functions.

Technical Characteristics / Substantial Equivalence:

The subject devices are identical to the predicate device except for minor technological differences. The C1 and EZ1 are single balloon devices that no longer have the fore balloon or extendable push rods. Since the fore balloon and push rods have been eliminated on the C1 and EZ1, the base handle of the subject devices has been simplified. The C1 and EZ1 both have a flexible nose cone attached to the distal end of the sleeve so that the sleeve terminates with an atraumatic tip. The nose cone for the C1 also serves as a component to attach the tool channel to the device. 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 C1, EZ1 and Tool Mount	**Predicate Device : Lumendi DiLumen C2 and Tool Mount (K211819)**
Classification	21 C.F.R. 876.1500, Product Code FDF	
Common name	Endoscope Accessory	
Intended Use / Indications for Use	The Lumendi DiLumen C1and EZ1 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 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.
Sterility	Non-sterile	Non-sterile
Single use/reusable	Single Use	Single Use
Balloons	Low durometer Polyurethane	Low durometer Polyurethane
Sleeve	Extruded polyurethane with main lumen having a hydrophilic coating.	Extruded polyurethane with main lumen having a hydrophilic coating.
Tool Channel Tubing (C1 only, EZ1 does not have a tool channel)	FEP; Pellethane; stainless steel internal coil	FEP; Pellethane; stainless steel internal coil
Number of Tool Channels	C1, one EZ1, none	Two
Nose Cone	PEBAX	None
Number of balloons	One	Two
Balloon Outer Diameter	60 mm	60 mm
Balloon Pressure	45 ± 12 mmHg	45 ± 12 mmHg
Relief Pressure	55 mmHg	55 mmHg
Working Length	130 cm and 103 cm	130 cm and 103 cm
Balloon Inflation Source	Manual inflation bulb	Manual inflation bulb
Shelf Life	24 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 C1 tool	A designated Tool Mount (DiLumen Tool Mount model D-4000) that is intended to mount to a surgical table rail and hold the

	Subject Device: **Lumendi DiLumen C1, EZ1 and Tool Mount**	**Predicate Device :** **Lumendi DiLumen C2 and Tool Mount (K211819)**
	channel during endoscopic treatment. The Tool Mount is made of stainless steel and is provided non-sterile. Note: DiLumen EZ1 does not have a Tool Channel and therefore the Tool Mount is not needed. The EZ1 does not have any designated accessories.	DiLumen C2 tool channels during endoscopic treatment. The Tool Mount is made of stainless steel and is provided non-sterile.

Performance Data:

Performance testing has demonstrated that the DiLumen C1 and EZ1 meet specifications and are as safe and effective as the predicate device. Bench testing primarily targeted verification of the balloon integrity and operation of the Device with an endoscope. The following performance data were provided in support of this 510(k) notice:

1. Instrument Insertion Force Test
2. Tool Channel Separation Force
3. Balloon Leak Force/Bond Leak Testing
4. Colon Grip Test
5. Fatigue/Cycling and System Leakage Test
6. Balloon Scope Centering Test
7. User Verification Test (Device Usability)

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

Conclusion:

In sum, the DiLumen C1 and EZ1 have 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. 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 C1, EZ1 and Tool Mount can be found substantially equivalent to the predicate DiLumen C2 and Tool Mount.