September 8, 2023

FUJIFILM Corporation
% Kotei Aoki
Senior Regulatory Affairs Specialist
Fujifilm Healthcare Americas Corporation
81 Hartwell Avenue
Suite 300
Lexington, Massachusetts 02421

Re: K223827
Trade/Device Name: FUJIFILM Endoscope Model EC-760S-A/L, Endoscopy Support Program EW10-VM01
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF, QTH
Dated: August 8, 2023
Received: August 8, 2023

Dear Kotei Aoki:

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 -S

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)*
K223827

Device Name
FUJIFILM Endoscope Model EC-760S-A/L
Endoscopy Support Program EW10-VM01

Indications for Use *(Describe)*

FUJIFILM Endoscope Model EC-760S-A/L
This product is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine. Never use this product for any other purposes.

Endoscopy Support Program EW10-VM01
This software provides image information to assist the user in estimating the size of an object displayed in the endoscopic field of view. This software provides no therapeutic or diagnostic function.

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

FUJIFILM Corporation

Endoscope Model EC-760S-A/L with Endoscopy Support Program EW10-VM01

August 7, 2023

Submitter's Information:
FUJIFILM Corporation
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ASHIGARAKAMI-GUN, KANAGAWA
258-8538 JAPAN

Contact Person:
Kotei Aoki
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Telephone: (765) 246-2931

Identification of the Proposed Device:

Device Name:	FUJIFILM Endoscope Model EC-760S-A/L
Common Name:	Colonoscope
Product Code:	FDF
Device Class:	Class 2
Regulation Number:	21 C.F.R 876.1500
Regulation Description:	Colonoscope And Accessories, Flexible/Rigid
Review Panel:	Gastroenterology/Urology

Device Name:	Endoscopy Support Program EW10-VM01
Common Name:	Virtual Scale
Product Code:	QTH
Device Class:	Class 2
Regulation Number:	21 C.F.R 876.1530
Regulation Description:	Endoscopic light-projecting measuring device
Review Panel:	Gastroenterology/Urology

Predicate Device(s):

- Endoscope Model EC-760S-V/L (K190649)
- AccuMeasure™ System (DEN210032)

Intended Use / Indications for Use:

FUJIFILM Endoscope Model EC-760S-A/L
This product is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine. Never use this product for any other purposes.

Endoscopy Support Program EW10-VM01
This software provides image information to assist the user in estimating the size of an object displayed in the endoscopic field of view. This software provides no therapeutic or diagnostic function.

Device Description:

FUJIFILM Endoscope Model EC-760S-A/L is comprised of three general sections: a control portion, an insertion portion and an umbilicus. The control portion controls the angulation of the endoscope. This portion also controls the flexibility of the distal end in the endoscope. The insertion portion contains glass fiber bundles, several channels and a complementary metal-oxide-semiconductor (CMOS) image sensor, and laser emitting window in its distal end. The channels in the insertion portion assist in delivering air/suction as well as endoscope accessories, such as forceps. The glass fiber bundles allow light to travel through the endoscope and emit light from the tip of the insertion portion to illuminate the body cavity. This provides enough light to the CMOS image sensor to capture an image and display it on the monitor. The umbilicus consists of electronic components needed to operate the endoscope when plugged in to the video processor and the light source. The endoscope is used in combination with the Company's video processors, light sources and peripheral devices such as monitor, printer, foot switch, and cart.

Endoscopy Support Program EW10-VM01 is a software-only device that detects the laser spot position of the dedicated endoscope in the image obtained via the video processor and displays a superimposed scale ("Virtual Scale") in the endoscopic image (e.g., displayed in a monitor). The Virtual Scale images can be either linear or circular. The virtual scale shows the graduated markings at 5mm, 10mm, and 20mm. EW10-VM01 must be installed on a personal computer (PC) that meets the mandatory system requirements for it to function. When the PC with EW10-VM01 connects to the video processor and the Virtual Scale function is turned ON. EW10-VM01 automatically retrieves the calibration data from the EC-760S-A/L. EW10-VM01 uses the data from the calibration table and detects the relative position of the red laser beam in the endoscopic image. EW10-VM01 superimposes the virtual scale images in the endoscopic image in real-time. The virtual scale acts as the virtual reference for the users to estimate sizes.

Comparison of Technological Characteristics:

A comparison of technological characteristics between the proposed device and the predicate device is provided in Table 1:

Table 1 Comparison of EC-760S-A/L and EC-760S-V/L (K190649)

		Proposed Device Endoscope Model EC-760S-A/L	Predicate Device Endoscope Model EC-760S-V/L (K190649)
Indications for Use (IFU)		This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.	
Virtual Scale Function		Available	Not available
Laser diode	For Virtual Scale Function	Yes Wavelength :637nm	No
	For optical communication	Yes Wavelength :1310nm	
Viewing direction		Forward/ 0 degree	
Observation range		2mm – 100mm	
Field of view		170 degrees	
Image sensors		CMOS	
Distal end diameter		12.8mm	
Flexible portion diameter		12.8mm	
Maximum insertion diameter		14.3mm	
Bending capability	UP	180 degrees	
	Down	180 degrees	
	Left	160 degrees	

	Proposed Device Endoscope Model EC-760S-A/L	Predicate Device Endoscope Model EC-760S-V/L (K190649)
Right	160 degrees	
Instrument channel diameter	3.8mm	
Working length / Total length	1690mm / 2010mm	
WJ function	YES	
Location of WJ Inlet	On the light guide connector	
Video/Lightguide Connector (Power supply method) (Communication method)	Scope Connector (Electromagnetic induction) (Optical communication)	
Connector CPU/Software	Installed	
Light source/Video processor	BL-7000/VP-7000	
Compatible accessories	Water Tank (WT-603)	
	Endoscopic Accessories	
	Electrosurgical Instruments	
	Air leak tester (LT-7F)	
Standard accessories	Suction Channel Brush (WB7025DC)	
	Cylinder/Inlet Brush (WB11003DV)	
	Distal End Brush (WB1318DE)	
	Cleaning Adapter (CA-610, CA-611)	
	Forceps Valve (FOV-DV7)	
	Ventilation Adapter (AD-7)	
	J Tube (JT-500)	
	Air/Water valve (AW-603)	
	Suction valve (SB-605)	
	Water Jet Inlet Cap	
Flexibility adjustment mechanism	Advanced Force Transmission, Adaptive Bending	
Control portion	G7 control portion	
FICE	Available	
BLI	Available	
BLI-bright	Available	
LCI	Available	

Table 2 Comparison of EW10-VM01 and AccuMeasure™ System (DEN210032)

	Proposed Device Endoscopy Support Program EW10-VM01	**Predicate Device AccuMeasure™ System (DEN210032)**
Intended Use	This software provides image information to assist the user in estimating the size of an object displayed in the endoscopic field of view. This software provides no therapeutic or diagnostic function.	The AccuMeasure System is intended to be used as an accessory in conjunction with an endoscope to measure observable anatomy and pathology in the gastrointestinal tract. The AccuMeasure System provides no therapeutic or diagnostic function.
Product code, Device class	QTH, Class II	
Review Panel	Gastroenterology/Urology	
Physical State	FUJIFILM Endoscope Model EC-760S-A/L is a dedicated endoscope that can emit a red laser beam from the distal end of the insertion portion by the laser diode.	The device consists of a measuring device and a processing unit. The measuring device includes a laser source at the proximal end and a probe at the distal end. The processing unit

	Proposed Device **Endoscopy Support Program EW10-VM01**	**Predicate Device** **AccuMeasure™ System** **(DEN210032)**
	Endoscopy Support Program EW10-VM01 is a software-only device installed on a personal computer (PC) and it is used in conjunction with an endoscopic video processing system. The laser spot from EC-760S-A/L is visible on the tissue surface and appears in the endoscopic image. EW10-VM01 detects the laser spot position by referencing the endoscopic image obtained via the video processor and displays a superimposed scale in the endoscopic image in real-time. The software does not have a measuring function—the software only calibrates the virtual scale (e.g., by the object recognition), and does not estimate the measurement by itself.	includes a medical grade PC, touchscreen monitor, video grabber, and device specific software.
Technical Method	EC-760S-A/L can emit a red laser beam from the distal end of the insertion portion by the laser diode. EW10-VM01 detects the position of the laser spot emitted from the distal end of the EC-760S-A/L insertion portion that appears in the endoscopic image, which is obtained via the video processor. EW10-VM01 displays a superimposed scale (“virtual scale”) in the endoscopic image (e.g., displayed in a monitor) with the graduated markings along the virtual scale.	The device is an endoscope accessory that is inserted through the instrument channel. During use, the measuring device projects a line over a structure on a mucosal surface. An endoscopic image of the structure is taken and then the user can select any two points along the projected line in the image. The device-based software calculates the distance between the selected points.
Measurement principle	Triangulation principle Reference point: 1	Triangulation principle Reference points: 2
Using laser for measurement	Red laser (from Endoscope) Wavelength :637nm	Red laser Wavelength :650nm
Using Laser pattern, safety class	One spot laser (from Endoscope) IEC60825-1 Class 1	One line laser IEC60825-1 Class 2
Endoscope Light source Video processor	EC-760S-A/L BL-7000 VP-7000	The AccuMeasure™ System is compatible with commercially available flexible colonoscopes and gastroscopes having working channels of ≥ 3.2 mm in diameter, and both Standard-Definition and High-Definition endoscopy systems are supported.
Type of illumination light for observation	4 LED light from Light source	Light from Light source (Includes 4 LED light when used in combination with our company light source BL-7000)
Target Area	Mucosal surfaces	
	Ineffective treatment due to the device providing inaccurate measurements	

	Proposed Device Endoscopy Support Program EW10-VM01	Predicate Device AccuMeasure™ System (DEN210032)
Identified Risks to Health	Device failure/malfunction leading to injury	
	Device failure due to interference with other devices[1]	
	Adverse tissue reaction[1]	
	Extended procedure time leading to increased adverse events[1]	
	Infection[1]	

[1] Evaluated with FUJIFILM Endoscope Model EC-760S-A/L. Endoscopy Support Program EW10-VM01 is software-only device.

Performance Data:

EC-760S-A/L is supplied non-sterile and must be properly reprocessed prior to use in accordance with the reprocessing instructions. Validation of the cleaning, disinfection, and sterilization instructions was performed in accordance with FDA's guidance, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, issued March 17, 2015.

EC-760S-A/L contains patient contacting material. Biocompatibility of the proposed device was evaluated using the following consensus standards: ISO 10993-1, ISO 10993-5, and ISO 10993-10. Biocompatibility testing was performed in accordance with FDA's guidance, *Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'*, issued September 4, 2020.

EC-760S-A/L contains electronic components. Electromagnetic compatibility, electrical safety, and thermal safety were evaluated using following standards: IEC 60601-1: 2005/(R)2012 and A1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010/AMD1:2013, and IEC 60601-2-18:2009.

Laser safety and photobiological safety of Endoscope Model EC-760S-A/L were evaluated using the following standards: IEC 60825-1:2007 and IEC 62471:2006.

Software of EC-760S-A/L and EW10-VM01 were evaluated using IEC 62304:2015 and in accordance with FDA's guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued May 11, 2005, and *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued October 2, 2014.

Endoscope specific testing was conducted according to ISO 8600-1:2015.

Accuracy of Virtual Scale images with Endoscopy Support Program EW10-VM01 has been evaluated.

in-vivo performance testing of visualization of laser spot with EW10-VM01 has been evaluated.

Conclusions:

The proposed device FUJIFILM Endoscope Model EC-760S-A/L and Endoscopy Support Program EW10-VM01 share the intended use and indications for use as the respective predicate device. EC-760S-A/L is additionally similar in technological characteristics and principle of operation to EC-760S-V/L (K190649). The differences have been evaluated for the biocompatibility, electrical safety, EMC, software, laser safety, photobiological safety, and bench testing. There remains no new concern regarding the safety and effectiveness of the proposed devices compared to the predicate devices. Thus, FUJIFILM Endoscope Model EC-760S-A/L and Endoscopy Support Program EW10-VM01 are substantially equivalent to the respective predicate device, Endoscope Model EC-760S-V/L (K190649) and AccuMeasure™ System (DEN210032).