August 19, 2022

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

Re: K221238
Trade/Device Name: FUJIFILM Ultrasonic Endoscope EG-740UT
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODG, FDS, ITX
Dated: July 20, 2022
Received: July 20, 2022

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, 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)*

K221238

Device Name
FUJIFILM Ultrasonic Endoscope EG-740UT

Indications for Use *(Describe)*

FUJIFILM Ultrasonic Endoscope EG-740UT is intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, diagnosis, and endoscopic treatment. This product is intended to be used with a FUJIFILM ultrasonic processor.
This product is not intended for use on children and infants.

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.

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510(k) Summary

FUJIFILM Corporation

FUJIFILM Ultrasonic Endoscope EG-740UT

Date: April 28, 2022

Submitter's Information:
FUJIFILM Corporation
798 MIYANODAI KAISEI-MACHI
ASHIGARAKAMI-GUN, KANAGAWA
258-8538 JAPAN

Contact Person:
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Identification of the Proposed Device:

Device Name:	FUJIFILM Ultrasonic Endoscope EG-740UT
Common Name:	Ultrasonic Endoscope
Product Code:	ODG; FDS, ITX
Device Class:	II
Regulation Number:	21 CFR 876.1500; 21 CFR 892.1570
Regulation Description:	Endoscope and accessories; Diagnostic ultrasonic transducer
Review Panel:	Gastroenterology/Urology

Predicate Device:

- FUJIFILM Ultrasonic Endoscope EG-580UT (K183433)

Reference Devices:

- Olympus GF Type UCT180 (K093395)
- FUJIFILM Endoscope Model EG-740N (K182836)

Intended Use / Indications for Use:

FUJIFILM Ultrasonic Endoscope EG-740UT is intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, diagnosis, and endoscopic treatment. This product is intended to be used with a FUJIFILM ultrasonic processor.

This product is not intended for use on children and infants.

Device Description:

FUJIFILM Ultrasonic Endoscope EG-740UT 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 charge-coupled device (CCD) image sensor 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 CCD 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 into the video processor, light source, and ultrasonic processor. The endoscopes are used in combination with FUJIFILM's video processors, light sources, ultrasonic processors, and peripheral devices such as monitor, printer, foot switch, and cart.

Comparison of Technological Characteristics:

The comparison is presented in Table 1.

Table 1

	Proposed device (to be assigned)	**Predicate device (K183433)**	**Reference 1 (K182836)**	**Reference 2 (K093395)**
Device name	Ultrasonic Endoscope EG-740UT	Ultrasonic Endoscope EG-580UT	GF Type UCT180	Endoscope Model EG-740N
Indications for use	[This product is] intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, diagnosis, and endoscopic treatment. This product is intended to be used with a FUJIFILM ultrasonic processor. This product is not intended for use on children and infants.			
Endoscopic specification				
Viewing direction	40 degrees			
Observation range	3-100 mm			
Field of view	140 degrees			
F# of the objective lens	4.9			
Resolution (Acceptance Criteria)	At 5mm of working distance: 0.08mm of line pair on the square wave chart is readable.			
	At 100mm of working distance: 1.4mm of line pair on the square wave chart is readable.			
Distortion characteristics	Orthogonal Projection			
Magnification of lens(es)	0.2-0.01			
Focal length	0.7 mm			
Image sensors	CCD			
Distal end diameter	14.5 mm	13.9 mm	14.6 mm	
Insertion portion diameter	12.6 mm	12.4 mm	12.6 mm	

Table 1 (continued)

		Proposed device (to be assigned)	Predicate device (K183433)	Reference 1 (K093395)	Reference 2 (K182836)
Instrument channel diameter		4.0 mm	3.8 mm		
Maximum insertion diameter		15.6 mm	15.0 mm	15.85 mm	
Working length		1250mm			
Bending capability	Up	150 degrees			
	Down	100 degrees	150 degrees	90 degrees	
	Left	100 degrees	120 degrees	90 degrees	
	Right	100 degrees	120 degrees	90 degrees	
Control portion		G7			
Scope Connector		One Step Connector	LG Connector; Video Connector		
CPU/Software (for contact-free Scope Connector)		Installed	N/A		Installed
Ultrasound specification					
Scanning method		Electrical convex scanning method			
Scanning direction		Same as the insertion direction of the endoscope			
Compatible Peripherals and Standard Accessories					
Compatible Peripherals		Video processing system (VP-7000, BL-7000)	Video processing system (EPX-4440HD, EPX-7000)		
		Water Tank (WT-603)	Water Tank (WT-2, WT-4)		
		Balloon (BS-102)	Balloon (B20UT)		
		Ultrasonic cable (UC-01)	Not included		
		Air leak tester (LT-7F)			
		Suction Unit[1]			
		Mouthpiece (MPC-ST)			
		Foot Switch (FS1)			
		Electrosurgical instruments			
		Monitor, Printer, Cart			
		Ultrasonic processors (SU-1, SU-1 PLATINUM)			
Standard Accessories		Forceps valve (FV-002)	Forceps valve (FOV-LL2)		
		Built in the scope connector	US waterproof cap (WA-7000)		
		Balloon attachment tool (BA-03)	Balloon attachment tool (BA-1)		
		Balloon channel brush (WB2517DC)	Balloon channel brush (WB2221FW2)		
		Air/Water valve (AW-602)			
		Suction valve (SB-604)			
		Air/Water channel cleaning adapter (CA-609)			
		Cleaning adapter (CA-608)			
		Ventilation adapter (AD-7)			
		Cleaning brushes (WB11003DV, WB7025DC, WB1318DE)			

Performance Data:

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*, published March 17, 2015.

Biocompatibility of the proposed device was evaluated using the following consensus standards: ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-10:2010. Biocompatibility testing was conducted in accordance with the FDA 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.

Electrical safety and EMC of the proposed device was evaluated using following standards: ANSI/AAMI ES 60601-1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-2-18:2009, and IEC 60601-2-37:2015.

Laser safety and photobiological safety of the proposed device was evaluated using the following standards: IEC 60825-1:2007 and IEC 62471:2006.

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

The proposed device met performance specifications in the following additional testing:

- Field of view
- Bending capability
- Rate of air supply
- Rate of water supply
- Rate of balloon water supply
- Rate of suction
- Rate of balloon suction
- Working length
- Diameter of forceps channel
- Viewing direction
- Resolution
- LG output
- Axial resolution
- Lateral resolution
- Penetration depth

Usability testing was conducted according to IEC 62366-1:2015 and the FDA guidance, *Applying Human Factors and Usability Engineering to Medical Devices*, issued February 3, 2016.

Conclusion:

The proposed device, FUJIFILM Ultrasonic Endoscope EG-740UT, share the same intended use and indications for use as, similar technological characteristics to, the same principles of operation as, and similar materials to the predicate device and the reference devices. The differences in technological characteristics and materials have been validated through the biocompatibility, the electrical safety, the EMC testing, and the bench testing. The testing demonstrates that the proposed device remains as safe and effective as the predicate device and there remains no new concern regarding the safety and effectiveness. FUJIFILM Ultrasonic Endoscope EG-740UT is substantially equivalent to the predicate device, FUJIFILM Ultrasonic Endoscope EG-580UT (K183433).