August 4, 2022

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

Re: K221952
Trade/Device Name: Endoscope Model EG-580UT and Endoscope Model EG-580UR
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODG, FDS, ITX
Dated: June 30, 2022
Received: July 5, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221952

Device Name
Endoscope Model EG-580UT
Endoscope Model EG-580UR

Indications for Use *(Describe)*

Endoscope Model EG-580UT
FUJIFILM Endoscope Model EG-580UT 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.

Endoscope Model EG-580UR
FUJIFILM Endoscope Model EG-580UR 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

Endoscope Models EG-580UT and EG-580UR

Date: June 30, 2022

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

Contact Person:
Kotei Aoki
Senior Regulatory Affairs Specialist
E-Mail: kotei.aoki@fujifilm.com
Telephone: (765) 246-2931

Identification of the Proposed Device:

Device Name:	Endoscope Models EG-580UT and EG-580UR
Common Name:	Endoscope
Product Code:	ODG FDS ITX
Device Class:	II
Regulation Number:	876.1500 (ODG, FDS) 892.1570 (ITX)
Regulation Description:	Endoscopic Ultrasound System, Gastroenterology-Urology Gastroscope And Accessories, Flexible/Rigid Transducer, Ultrasonic, Diagnostic
Review Panel:	Gastroenterology/Urology

Predicate Device(s):

- Endoscope Models EG-580UT and EG-580UR (K183433)

Intended Use / Indications for Use:

Endoscope Model EG-580UT
FUJIFILM Endoscope Model EG-580UT 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.

Endoscope Model EG-580UR
FUJIFILM Endoscope Model EG-580UR 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:

Endoscope Models EG-580UT and EG-580UR are 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 or diagnostic ultrasound systems, and peripheral devices such as monitor, printer, foot switch, and cart.

Comparison of Technological Characteristics:

A comparison of technological characteristics between the proposed device and the predicate device is provided in the Tables below:

Table 1 Comparison of the proposed device to the predicate device, EG-580UT

		Proposed device EG-580UT (to be assigned)	**Predicate device EG-580UT (K183433)**
Indications for use (IFU)		FUJIFILM Endoscope Model EG-580UT 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		3-100mm	
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		0.7mm	
Image sensors		CCD	
Distal end diameter		13.9mm	
Insertion portion diameter		12.4mm	
Maximum insertion diameter		15.0mm	
Bending capability	Up	150 degrees	
	Down	150 degrees	
	Left	120 degrees	
	Right	120 degrees	
Forceps channel diameter		3.8mm	
Working length, Total length		1250mm, 1550mm	
Operation portion		G7	
Video processor/Light source		VP-4440HD / XL-4450	

	VP-7000 / BL-7000	
Peripherals	Water Tank (WT-2, WT-4)	
	Balloon (B20UT)	
	Air leak tester (LT-7F)	
Accessories	Forceps valve (FOV-LL2)	
	Air/Water valve (AW-602)	
	Suction valve (SB-604)	
	US waterproof cap (WA-7000)	
	Balloon attachment tool (BA-1)	
	Ventilation Adapter (AD-7)	
	Cleaning Adapter (CA-608)	
	Air/Water channel cleaning adapter (CA-609)	
	Cleaning brushes (WB11003DV, WB7025DC, WB2221FW2, WB1318DE)	
Ultrasound specification		
Scanning method	Electronic convex scanning method	
Scanning direction	Same as the insertion direction of the endoscope	
Ultrasonic processor	SU-1, SU-1 Platinum	
Diagnostic ultrasound system	ALOKA ARIETTA 850 (K183456)	Not compatible

Table 2 Comparison of the proposed device to the predicate device, EG-580UR

		Proposed device EG-580UR (to be assigned)	**Predicate device EG-580UR (K183433)**
Indications for use (IFU)		FUJIFILM Endoscope Model EG-580UR 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		0 degree (Forward view)	
Observation range		3-100mm	
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		0.7mm	
Image sensors		CCD	
Distal end diameter		11.4mm	
Insertion portion diameter		11.5mm	
Maximum insertion diameter		12.7mm	
Bending capability	Up	190 degrees	
	Down	90 degrees	
	Left	100 degrees	
	Right	100 degrees	
Forceps channel diameter		2.8mm	
Working length, Total length		1250mm, 1550mm	

Operation portion	G7	
Video processor/Light source	VP-4440HD / XL-4450 VP-7000 / BL-7000	
Peripherals	Water Tank (WT-2, WT-4)	
	Balloon (B20UR)	
	Air leak tester (LT-7F)	
Accessories	Forceps Valve (FOV-DV7)	
	Air/Water valve (AW-602)	
	Suction valve (SB-604)	
	US waterproof cap (WA-7000)	
	Balloon attachment tool (BA-1)	
	Ventilation Adapter (AD-7)	
	Cleaning Adapter (CA-608)	
	Air/Water channel cleaning adapter (CA-609)	
	Cleaning brushes (WB11003DV, WB7025DC, WB2221FW2, WB1318DE)	
Ultrasound specification		
Scanning method	Electrical radial array	
Scanning direction	Perpendicular to the insertion direction of the ultrasonic endoscope	
Ultrasonic processor	SU-1, SU-1 Platinum	
Diagnostic ultrasound system	ALOKA ARIETTA 850 (K183456)	Not compatible

Performance Data:

The proposed devices are adopted into the reprocessing validation of the predicate device, which was conducted in accordance with the FDA guidance, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, issued on March 17, 2015.

The proposed devices are adopted into the biocompatibility testing of the predicate device, which was conducted in accordance with ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-10:2010 and 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.

EMC and ultrasonic endoscopic safety of the proposed device were evaluated using following standards: IEC 60601-1-2:2014 and IEC 60601-2-37:2007+A1:2015.

The acoustic output of the proposed devices was evaluated with the ALOKA ARIETTA 850 in accordance with the FDA guidance, *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*, issued June 27, 2019.

The proposed devices are adopted into the performance testing of the predicate device, which was conducted in accordance with ISO 8600-1:2015.

Conclusions:

The proposed devices share the same intended use, physical characteristics, and principle of operation as the predicate device. The differences have been evaluated for the EMC, ultrasound endoscopic safety, and acoustic output. There remains no new concern regarding the safety and effectiveness of the proposed device. Thus, the proposed devices EG-580UT and EG-580UR are substantially equivalent to the predicate devices, Endoscope Models EG-580UT and EG-580UR (K183433).