January 27, 2023

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

Re: K221551
Trade/Device Name: FUJIFILM Endoscope Model EI-740D/S
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS, FAM
Dated: December 22, 2022
Received: December 22, 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 -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)*

K221551

Device Name
FUJIFILM Endoscope Model EI-740D/S

Indications for Use *(Describe)*
FUJIFILM Endoscope Model EI-740D/S is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

This device is also intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and sigmoid colon.

Never use this product for any other purposes.

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 Endoscope Model EI-740D/S

Date: May 25, 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:	FUJIFILM Endoscope Model EI-740D/S
Common Name:	Endoscope
Product Code:	FDS, FAM
Device Class:	II
Regulation Number:	876.1500
Regulation Description:	Endoscope and accessories
Review Panel:	Gastroenterology/Urology

Predicate Device(s):

- Endoscope Model EI-740D/S (K210162)

Intended Use / Indications for Use:

FUJIFILM Endoscope Model EI-740D/S is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

This device is also intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and sigmoid colon.

Never use this product for any other purposes

Device Description:

FUJIFILM Endoscope Model EI-740D/S is comprised of three general sections: a control portion, an insertion portion and an umbilicus. The control portion controls the angulation of 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 in to the video processor and the light source. The endoscope is used in combination with FUJIFILM's video processor, FUJIFILM's light sources 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 Table 1:

Table 1 Comparison of the features

		Proposed Device **FUJIFILM Endoscope** **Model EI-740D/S** (To be assigned)	Predicate Device FUJIFILM Endoscope Model EI-740D/S (K210162)
Indications for Use (IFU)		FUJIFILM Endoscope Model EI-740D/S is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum. This device is also intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and sigmoid colon. Never use this product for any other purposes.	
Light Source/Video Processor		BL-7000/VP-7000 BL-7000X/VP-7000 EP-6000	BL-7000/VP-7000 EP-6000
Oxygen Saturation Image Processor		EX-0	Not Available
Delayed Reprocessing		Yes	No
Viewing direction		Forward/ 0 degree	
Observation range		3mm-100mm	
Field of View		140 degrees	
Distal end diameter		12.8mm	
Flexible portion diameter		12.8mm	
Maximum insertion diameter		14.3mm	
Bending capability	Up	210 degrees	
	Down	90 degrees	
	Right	100 degrees	
	Left	100 degrees	
Forceps channel diameter		(1st Channel) 3.2mm (2nd Channel) 3.7mm	
Working length		1030mm	
Total length		1330mm	
FICE		Available	
BLI		Available	
BLI-bright		Available	
LCI		Available	
OXEI mode		Available	Not Available

Performance Data:

The proposed device was adopted into the cleaning, disinfection, and sterilization validation of the predicate device. Validation of the delayed reprocessing instructions was performed in accordance with

the FDA's guidance, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, issued March 17, 2015.

The proposed device was adopted into the StO_2 measurement (in OXEI mode) testing performed on the EX-0 Oxygen Saturation Image Processor paired with the Endoscope Model EG-740N (K203717).

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

Photobiological safety of the proposed device were evaluated using the following standard: IEC 62471:2006.

No modification has been proposed in the material construction, patient contact type/duration, or other technological characteristics. The proposed device FUJIFILM Endoscope Model EI-740D/S can be adopted into the biocompatibility and the performance testing of the Endoscope Model EI-740D/S (K210162).

Conclusions:

The proposed device FUJIFILM Endoscope Model EI-740D/S shares the same intended use and indications, materials of construction, and electrical components as the predicate device. The reprocessing validation demonstrates that the proposed device can be cleaned as effective as the predicate device. Thus, FUJIFILM Endoscope Model EI-740D/S is substantially equivalent to the predicate device, Endoscope Model EI-740D/S (K210162).