April 9, 2021

FUJIFILM Corporation
% Jeffrey Wan
Senior Regulatory Affairs Specialist
FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K210162
Trade/Device Name: 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: February 5, 2021
Received: February 8, 2021

Dear Jeffrey Wan:

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)*
K210162

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.

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 EI-740D/S

Date: February 5, 2021

Submitter's Information:
FUJIFILM Corporation
798 Miyanodai Kaisei-Machi
Ashigarakami-Gun, Kanagawa, Japan 258-8538

Contact Person:
Jeffrey Wan
Senior Regulatory Affairs Specialist
Telephone: (201) 675-8947
E-Mail: jeffrey.wan@fujifilm.com

Identification of the Subject Device:

Device Name:	FUJIFILM Endoscope Model EI-740D/S
Common Name:	Endoscope
Device Class:	Class II
Classification Number:	21 C.F.R. § 876.1500
Classification Name:	Endoscope and accessories
Device Panel:	Gastroenterology/Urology

Product Code Information:

Product Code Name	CFR Section	Product Code
Gastroscope and accessories, flexible/rigid	21 CFR 876.1500	FDS
Sigmoidoscope and accessories, flexible/rigid	21 CFR 876.1500	FAM

Predicate Devices:

FUJIFILM Endoscope Models EG-530D and ES-530WE (K142629)

Reference Device:

FUJIFILM Endoscope Model EC-740T/L (K183572)

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.

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 processors, light sources and peripheral devices such as monitor, printer, foot switch, and cart.

Comparison of Technological Characteristics

The subject device FUJIFILM Endoscope Model EI-740D/S differs from the predicate devices in the following modifications:

- Dimensional and material changes to the insertion portion
- Addition of a 2nd forceps/instrument channel
- Compatibility with different cleaning adapters and forceps valve

Table 1 – Comparison of EI-740D/S to EG-530D for upper GI endoscopy

		Predicate Device	Reference Device	Subject Device
Device name		EG-530D	EC-740T/L	EI-740D/S
Common name		Gastroscope	Colonoscope	Endoscope
Manufacturer		FUJIFILM Corporation	FUJIFILM Corporation	FUJIFILM Corporation
510(k) number		K142629	K183572	K210162
Intended Use / Indications for Use		This device is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.	FUJIFILM Endoscope Model EC-740T/L is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.	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.
Viewing direction		Forward / 0 degrees	Forward / 0 degrees	Same as Predicate Device
Observation range		3mm – 100mm	3mm – 100mm	Same as Predicate Device
Field of view		140 degrees	140 degrees	Same as Predicate Device
Distal end diameter		11.5mm	9.8mm	12.8mm
Flexible portion diameter		11.5mm	10.7mm	12.8mm
Bending capability	**Up**	210 degrees	210 degrees	Same as Predicate Device
	Down	90 degrees	160 degrees	Same as Predicate Device
	Left	100 degrees	160 degrees	Same as Predicate Device
	Right	100 degrees	160 degrees	Same as Predicate Device
Forceps channel diameter		2.8mm	3.2mm	Same as Reference Device
2nd Forceps channel diameter		3.8mm	N/A	3.7mm
Working length		1090mm	1690mm	1030mm
Total length		1405mm	1990mm	1330mm
Video processor / Light source		VP-4440HD / XL-4450 VP-7000 / BL-7000 EP-6000	VP-7000 / BL-7000 EP-6000	Same as Reference Device

	Predicate Device	Reference Device	Subject Device
Peripherals	Water Tank WT-2, WT-4 Endoscopic Accessory (i.e. Forceps) Monitor Printer Electrosurgical Instruments Foot Switch Cart	Water Tank WT-603 Endoscopic Accessory (i.e. Forceps) Monitor Printer Electrosurgical Instruments Foot Switch Cart	Same as Reference Device
Standard accessories	Channel Cleaning Brush WB4321FW2 Cylinder/Port Cleaning Brush WB11002FW2 Cleaning Adapter CA-500D/A Forceps Valve FOV-DV7 Ventilation Adapter AD-7 J Tube JT-500 Air/Water Button AW-500 Suction Button SB-500 Water Jet Inlet Cap	Suction Channel Brush WB7025DC Cylinder/Inlet Brush WB11003DV Distal End Brush WB1318DE Cleaning Adapter CA-610 Air/Water Channel Cleaning Adapter 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	<u>Same as Reference Device:</u> Suction Channel Brush WB7025DC Cylinder/Inlet Brush WB11003DV Distal End Brush WB1318DE Air/Water Channel Cleaning Adapter CA-611 Ventilation Adapter AD-7 J Tube JT-500 Air/Water Valve AW-603 Suction Valve SB-605 Water Jet Inlet Cap <u>Introduced in this submission:</u> Cleaning Adapter CA-617 Forceps Valve FV-001
Optional accessories	Air leak tester LT-7F	Air leak tester LT-7F	<u>Same as Predicate Device:</u> Air leak tester LT-7F Forceps Valve FOV-DV7* *This accessory was changed from standard to optional. <u>Introduced in this submission:</u> Cleaning Adapter CA-614

Table 2 – Comparison of EI-740D/S to ES-530WE for sigmoidoscopy

	Predicate Device		Reference Device	Subject Device
Device name	ES-530WE		EC-740T/L	EI-740D/S
Common name	Sigmoidoscope		Colonoscope	Endoscope
Manufacturer	FUJIFILM Corporation		FUJIFILM Corporation	FUJIFILM Corporation
510(k) number	K142629		K183572	K210162
Intended Use / Indications for Use	This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and sigmoid colon.		FUJIFILM Endoscope Model EC-740T/L is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.	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.
Viewing direction	Forward / 0 degrees		Forward / 0 degrees	Same as Predicate Device
Observation range	3mm – 100mm		3mm – 100mm	Same as Predicate Device
Field of view	140 degrees		140 degrees	Same as Predicate Device
Distal end diameter	12.8mm		9.8mm	Same as Predicate Device
Flexible portion diameter	12.8mm		10.7mm	Same as Predicate Device
Bending capability	**Up**	180 degrees	210 degrees	Same as Reference Device
	Down	180 degrees	160 degrees	90 degrees
	Left	160 degrees	160 degrees	100 degrees
	Right	160 degrees	160 degrees	100 degrees
Forceps channel diameter	3.8mm		3.2mm	Same as Reference Device
2nd Forceps channel diameter	N/A		N/A	3.7mm
Working length	790mm		1690mm	1030mm
Total length	1090mm		1990mm	1330mm
Video processor / Light source	VP-4440HD / XL-4450 VP-7000 / BL-7000 EP-6000		VP-7000 / BL-7000 EP-6000	Same as Reference Device

	Predicate Device	Reference Device	Subject Device
Peripherals	Water Tank WT-2, WT-4 Endoscopic Accessory (i.e. Forceps) Monitor Printer Electrosurgical Instruments Foot Switch Cart	Water Tank WT-603 Endoscopic Accessory (i.e. Forceps) Monitor Printer Electrosurgical Instruments Foot Switch Cart	Same as Reference Device
Standard accessories	Channel Cleaning Brush WB4321FW2 Cylinder/Port Cleaning Brush WB11002FW2 Cleaning Adapter CA-500D/A Forceps Valve FOV-DV7 Ventilation Adapter AD-7 J Tube JT-500 Air/Water Button AW-500 Suction Button SB-500 Water Jet Inlet Cap	Suction Channel Brush WB7025DC Cylinder/Inlet Brush WB11003DV Distal End Brush WB1318DE Cleaning Adapter CA-610 Air/Water Channel Cleaning Adapter 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	<u>Same as Reference Device:</u> Suction Channel Brush WB7025DC Cylinder/Inlet Brush WB11003DV Distal End Brush WB1318DE Air/Water Channel Cleaning Adapter CA-611 Ventilation Adapter AD-7 J Tube JT-500 Air/Water Valve AW-603 Suction Valve SB-605 Water Jet Inlet Cap <u>Introduced in this submission:</u> Cleaning Adapter CA-617 Forceps Valve FV-001
Optional accessories	Air leak tester LT-7F	Air leak tester LT-7F	<u>Same as Predicate Device:</u> Air leak tester LT-7F Forceps Valve FOV-DV7* *This accessory was changed from standard to optional. <u>Introduced in this submission:</u> Cleaning Adapter CA-614

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 subject device was evaluated using the following standards:
ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-10:2010. 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,'" published June 16, 2016.

Software contained in the subject device was evaluated according to IEC 62304:2015 and the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," published May 11, 2005. Cybersecurity controls were developed according to the FDA guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," published October 2, 2014.

Electrical safety and electromagnetic compatibility of the subject device were evaluated using the following standards: ANSI/AAMI ES 60601-1: 2005/(R)2012 and A1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2013, and IEC 60601-2-18:2009.

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

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

Optical and color performance of the subject device when used with compatible video processors were evaluated according to well-established methods.

Additional performance specifications were evaluated against pre-defined acceptance criteria.

Conclusions

The subject device EI-740D/S shares the same intended use and substantially similar indications to the predicate devices. Bench testing demonstrates that the subject device is as safe and effective as the predicate devices. Thus, EI-740D/S is substantially equivalent to the listed predicate devices.