May 23, 2025

Fujifilm Corporation
% Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
FUJIFILM Healthcare Americas Corporation
81 Hartwell Ave Suite 300
Lexington, Massachusetts 02421

Re: K243261
Trade/Device Name: FUJIFILM Endoscope Model EC-860P/M; FUJIFILM Endoscope Model EC-860P/L; FUJIFILM Endoscope Model EC-860S/L
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF
Dated: April 25, 2025
Received: April 25, 2025

Dear Chaitrali Kulkarni:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243261

Device Name
FUJIFILM Endoscope Model EC-860P/M;
FUJIFILM Endoscope Model EC-860P/L;
FUJIFILM Endoscope Model EC-860S/L

Indications for Use *(Describe)*
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.

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) #: K243261

510(k) Summary

Prepared on: 2025-05-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Fujifilm Corporation
Applicant Address	798 MIYANODAI KAISEI-MACHI ASHIGARAKAMI-GUN KANAGAWA 258-8538 Japan
Applicant Contact Telephone	704-517-4886
Applicant Contact	Ms. Chaitrali Kulkarni
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Correspondent Name	FUJIFILM Healthcare Americas Corporation
Correspondent Address	81 Hartwell Ave Suite 300 Lexington MA 02421 United States
Correspondent Contact Telephone	704-517-4886
Correspondent Contact	Ms. Chaitrali Kulkarni
Correspondent Contact Email	hcusregulatoryaffairs@fujifilm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	FUJIFILM Endoscope Model EC-860P/M; FUJIFILM Endoscope Model EC-860P/L; FUJIFILM Endoscope Model EC-860S/L
Common Name	Endoscope and accessories
Classification Name	Colonoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FDF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172916	FUJIFILM Endoscope Model EC-760R-V/L	FDF
K190649	FUJIFILM Endoscope Model EC-760S-V/L	FDF
K183572	FUJIFILM Endoscope Models EC-760P-V/L	FDF
K222584	EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500, COLO	FET

Device Description Summary

21 CFR 807.92(a)(4)

A. Intended Use/indications for Use

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.

B. Technological characteristics

The insertion portion of the device has a mechanism (hereinafter "the bending portion") which bends the tip from right to left and up and down, and a flexible tube (hereinafter "the flexible portion") consists of the bending portion and operating portion with a knob which controls the bending portion. The forceps channel which runs through the operating portion to the tip is arranged inside the insertion portion for inserting the surgical instrument.
The insertion portion of the endoscopes comes into contact with the mucosal membrane.
The tip of the insertion portion is called the "Distal end" which contains the Imaging section, Distal cap, Objective lens, Air/water nozzle, Water jet nozzle, Instrument channel outlet, Objective lens, and Light guide.
The bending portion is controlled by knobs on the control portion/operation section to angulate the distal end to certain angles.
The Flexible portion refers to the long insertion area between the Bending portion and the Control portion (a part of Non-insertion portion). This portion contains light guides (glass fiber bundles), air/water channels, a forceps/suction channel, a CMOS image sensor, and cabling. The glass fiber bundles allow light to travel through the endoscope to illuminate the body cavity, thereby providing enough light to the CMOS image sensor to capture an image and display the image on a monitor. The forceps channel is used to introduce biopsy forceps and other endoscopic accessories, as well as providing suction.
The control portion/operating section provides a grip to grasp the endoscopes and contains mechanical parts to operate the endoscopes. This section includes a Forceps inlet, which allows endoscope accessories to be introduced. The Scope connector connects the endoscopes to the light source and video processor, respectively.

C. Principles of Operation

The Endoscope Model EC-860P/M, EC-860P/L, and EC-860S/L function on the same principles of operation as the predicate device. EC-860P/M, EC-860P/L, and EC-860S/L are endoscopes for observation, diagnosis, and treatment of the lower digestive tract. After connecting to the light source, the devices guide the light through the fiber bundles situated inside the insertion portion of the device. The light that emits from the distal end of the insertion portion reflects from the target region and forms an image on the CMOS image sensor through a group of object lenses placed at the distal end of the devices. An electric signal from the image sensor is transmitted to the video processor connected to the device. The video processor converts the electric signal into a video signal and displays an image on a monitor.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication for use for the proposed device and the predicate devices are same.

Technological Comparison

21 CFR 807.92(a)(6)

Proposed device models come with optical characteristics compared to predicate devices. Although the differences in the optical characteristics have been tested through Bench testing and no new concern for safety or efficacy was seen.

a) EC-860P/M
The difference in the F# and resolution of the objective lens in EC-860P/M compared to the predicate device does not affect the safety or efficacy of the subject device because of bench testing data demonstrated that the proposed devices are substantially equivalent in performance to the predicate devices.
Also proposed device model has differences in the distal end diameter and total length compared to the predicate device does not affect the safety or efficacy of the subject device because this value is between predicate and reference devices.
The proposed device models have differences in materials in comparison to the predicate devices. The differences in the materials have been tested through biocompatibility testing and no new concern for safety or efficacy was seen.

b) EC-860P/L
The difference in the F# and resolution of the objective lens in EC-860P/L compared to the predicate device does not affect the safety or efficacy of the subject device because of bench testing data demonstrated that the proposed devices are substantially equivalent in performance to the predicate devices.
Also proposed device model has differences in the distal end diameter compared to the predicate device does not affect the safety or

efficacy of the subject device because this value is same as reference device.
The proposed device models have differences in materials in comparison to the predicate devices. The differences in the materials have been tested through biocompatibility testing and no new concern for safety or efficacy was seen.

c) EC-860S/L
The difference in the F# and resolution of the objective lens in EC-860S/L compared to the predicate device does not affect the safety or efficacy of the subject device because of bench testing data demonstrated that the proposed devices are substantially equivalent in performance to the predicate devices.
Also proposed device model has differences in the distal end diameter, flexible portion diameter and maximum diameter compared to the predicate device does not affect the safety or efficacy of the subject device because this value is the same as reference device
The proposed device models have differences in materials in comparison to the predicate devices. The differences in the materials have been tested through biocompatibility testing and no new concern for safety or efficacy was seen.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Electrical safety of the subject device was evaluated using following standards: ANSI/AAMI ES 60601-1:2012, IEC 60601-1-2:2020, IEC60601-1-6:2020 and IEC 60601-2-18:2009.

Biocompatibility of the subject device was evaluated using the following consensus standards: ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-10:2021. Biocompatibility testing was conducted in accordance with the FDA guidance, Use of International Standards ISO 10993-1, "Biological evaluation of medical devices - Part 1 : Evaluation and testing within a risk management process", issued June 16,2016.

Endoscope specific testing was conducted using the following consensus standards: ISO 8600-1:2015, ISO 8600-3:2019, and ISO 8600-4:2014.

Software specific testing was conducted using the following consensus standards: IEC 62304:2015. The software validation activities were performed in accordance with the FDA Guidance,Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005.

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.

The subject device met performance specifications in the following additional testing:
- Field of view
- Diamater of forceps channel
- Uneven illumination
- Bending capability
- Viewing direction
- Color reproducibility
- Rate of suction
- Resolution
- Air volume
- Working length
- LG output
- Water volume

Bench testing data regarding "Optical performance" demonstrated that the subject devices are substantially equivalent in performance to the predicate devices.

The subject devices FUJIFILM Endoscope Model EC-860P/M, EC-860P/L and EC-860S/L are substantially equivalent to the predicate devices based on the same intended use, indications for use, similar technological characteristics and materials. The differences in technological characteristics and materials between the subject and predicate devices raise no new issues of safety or effectiveness. Bench testing data demonstrated that the subject devices are substantially equivalent in performance to the predicate devices. The difference in materials between subject and predicate devices has been validated through biocompatibility testing. Thus, the subject devices FUJIFILM Endoscope Model EC-860P/M, EC-860P/L and EC-860S/L are substantially equivalent to the predicate device, FUJIFILM Endoscope Model EC-760R-V/L(K172916).