April 11, 2025

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

Re: K243260
Trade/Device Name: FUJIFILM Processor EP-8000; FUJIFILM Endoscope Model EG-860R
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FET, NTN, NWB, PEA, FDS
Dated: March 12, 2025
Received: March 12, 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,

Sivakami Venkatachalam -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243260

Device Name

FUJIFILM Processor EP-8000;
FUJIFILM Endoscope Model EG-860R

Indications for Use *(Describe)*

a. Processor EP-8000

- The EP-8000 is an endoscopic processor with an integrated light source that is intended to provide illumination, process electronic signals transmitted from a video endoscope and enable image recording.
- This product can be used in combination with compatible medical endoscope, a monitor, a recorder and various peripherals.
- It supplies air through the endoscope, for obtaining clear visualization and is used for endoscopic observation, diagnosis and treatment.
- BLI (Blue Light Imaging), LCI (Linked Color Imaging), ACI (Amber-red Color Imaging) and FICE (Flexible spectral-Imaging Color Enhancement) are adjunctive tools for gastrointestinal endoscopic examinations which can be used to supplement Fujifilm white light endoscopy. BLI, LCI, ACI and FICE are not intended to replace histopathological sampling as a means of diagnosis.

b. Endoscope Model EG-860R
This product is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

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.

510(k) #: K243260

510(k) Summary

Prepared on: 2025-03-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Fujifilm Corporation
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Correspondent Contact	Ms. Chaitrali Kulkarni
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	FUJIFILM Processor EP-8000; FUJIFILM Endoscope Model EG-860R
Common Name	Endoscopic video imaging system/component, gastroenterology-urology
Classification Name	Endoscope and accessories
Regulation Number	876.1500
Product Code(s)	FET, NTN, NWB, PEA, FDS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K163675	Processor VP-7000, Light Source BL-7000	FET
K172916	FUJIFILM Endoscope Model EG-760R	FDS
K240142	FUJIFILM Endoscope Model EG-840N, EG-840T	FDS

Device Description Summary

21 CFR 807.92(a)(4)

A. Intended Use/indications for Use

a. Processor EP-8000

• The EP-8000 is an endoscopic processor with an integrated light source that is intended to provide illumination, process electronic signals transmitted from a video endoscope and enable image recording.
• This product can be used in combination with compatible medical endoscope, a monitor, a recorder and various peripherals.
• It supplies air through the endoscope, for obtaining clear visualization and is used for endoscopic observation, diagnosis and treatment.
• BLI (Blue Light Imaging), LCI (Linked Color Imaging), ACI (Amber-red Color Imaging) and FICE (Flexible spectral-Imaging Color Enhancement) are adjunctive tools for gastrointestinal endoscopic examinations which can be used to supplement Fujifilm white light endoscopy. BLI, LCI, ACI and FICE are not intended to replace histopathological sampling as a means of diagnosis.

b. Endoscope Model EG-860R
This product is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

B. Technological characteristics

a. Processor EP-8000
FUJIFILM Video Processor EP-8000 is intended to provide illumination, process electronic signals transmitted from a video endoscope and enable image recording.

FUJIFILM Video Processor EP-8000 relays the image from an endoscope to a video monitor. The projection can be either analog or digital at the user's preference. The processor employs fiber bundles to transmit light from four LED lamps (Violet, Blue, Green, and Amber) , with a total power of 79.2W lamps, to the body cavity.

The EP-8000, like the VP-7000 and BL-7000, has additional image processing options called BLI, BLI-bright, and LCI that provide endoscopic assistance for white light imaging (WLI). There is also an additional image processing option called "ACI"(Amber-red Color Imaging).

ACI is an image processing function that simultaneously emphasizes the brightness and color difference of red information in endoscopic images and serves as an adjunct to white light imaging (WLI).
Compared to WLI mode, ACI relatively increases the ratio of amber red light and decreases the ratio of violet light.
Relatively high-saturation red information such as blood-like red in the image signal digitized by the camera unit is enhanced by signal processing.

The EP-8000 also has a Multi Observation option that allows endoscopic images to be displayed in the main screen area and sub-screen area by switching image processing options at every frame. This allows each image frame to be displayed in the main screen area and sub-screen area 1 with a different combination of image processing options applied [WLI+(LCI), LCI+(WLI), BLI+(WLI), WLI+(BLI)].

The device is AC operated at a power setting of 100-240V/50-60Hz/ 3.0-1.5A. The processor is housed in a steel-polycarbonate case measuring 395×210×515mm

b. Endoscope Model EG-860R
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

a. Processor EP-8000
The subject device, FUJIFILM Video Processor EP-8000, combines the principles of operation of the predicate devices, FUJIFILM Video Processor VP-7000 and Light Source BL-7000. EP-8000 is intended to provide illumination, process electronic signals transmitted from a video endoscope during the endoscopic observation, diagnosis, treatment, and image recording.

After connecting to the light source and processor, 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.on a monitor.

b.EG-860R
The Endoscope Model EG-860R function on the same principles of operation as the predicate device. EG-860R is endoscopes for observation, diagnosis, and treatment of the upper 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)

a. Processor EP-8000

- The EP-8000 is an endoscopic processor with an integrated light source that is intended to provide illumination, process electronic signals transmitted from a video endoscope and enable image recording.
- This product can be used in combination with compatible medical endoscope, a monitor, a recorder and various peripherals.
- It supplies air through the endoscope, for obtaining clear visualization and is used for endoscopic observation, diagnosis and treatment.
- BLI (Blue Light Imaging), LCI (Linked Color Imaging), ACI (Amber-red Color Imaging) and FICE (Flexible spectral-Imaging Color Enhancement) are adjunctive tools for gastrointestinal endoscopic examinations which can be used to supplement Fujifilm white light endoscopy. BLI, LCI, ACI and FICE are not intended to replace histopathological sampling as a means of diagnosis.

b. Endoscope Model EG-860R
This product is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

Indications for Use Comparison

21 CFR 807.92(a)(5)

a. Processor EP-8000
This product is an endoscopic processor with an integrated light source that is intended to provide illumination, process electronic signals transmitted from a video endoscope and enable image recording.
This product can be used in combination with compatible medical endoscope, a monitor, a recorder and various peripherals.
It supplies air through the endoscope, for obtaining clear visualization and is used for endoscopic observation, diagnosis and treatment.
These indications for use are nearly identical to those of the predicate device Processor VP-7000 and Light source BL-7000(K163675), except for the addition of language providing clarification about the use of the ACI feature of the device. The company makes no ACI-specific claims in the indications for use or the labeling.
These minor additions do not affect the diagnostic use of the device relative to the predicates, as they merely provide clarification around the use of ACI with the system.

b. Endoscope Model EG-860R
The indication for use for the proposed device and the predicate devices are same.

Technological Comparison

21 CFR 807.92(a)(6)

a. Processor EP-8000

The subject and predicate devices share the same mode of operation, number of LED lamps used for light transmission and intended

use. The subject device is unchanged from the Predicate device's BL-7000, which uses the same four LED colors: violet, blue, green, and amber. The subject device differs from the predicate devices VP-7000 and BL-7000 in terms of technological characteristics.

A summary of major differences between the subject device EP-8000 and the predicate devices VP-7000 and BL-7000 is provided as follows:

• The subject device is comprised of one unit that provides both video processing and sourcing functions. The predicate devices separate the two functions into two separate. Risk analysis showed that having one unit for both video and sourcing function does not affect the safety of efficacy of the subject device.

• The power rating is modified from 0.8-0.5A(VP-7000), 1.2-0.7A(BL-7000) to 2.0-1.1A. IEC testing was performed on the subject device, the difference in power rating does not increase the safety or efficacy of the subject device.

• The subject device is compatible with the following.
【Gastrointestinal endoscope】 800 System endoscopies,700 System endoscopies,600 System endoscopies,500 System endoscopies.
The difference in the compatible endoscope systems does not affect the safety or efficacy of the subject device, the compatible scopes are listed on the Operation Manual for EP-8000.

• The subject device is compatible with the DK-8000E keyboard, whereas the predicate
devices are compatible with the DK-7000E keyboard. The difference in compatible keyboard does not affect the safety or efficacy of the subject device, the compatible keyboard is provided with EP-8000.

• User modes changes from FICE, BLI, BLI-bright and LCI to FICE, BLI, BLI-bright ,LCI and ACI. Color Performance testing was performed on EP-8000, the addition of ACI user mode does not increase the safety or efficacy of the subject device.

• The subject device does not offer analog output via Y/C and analog input. Not having the analog output via Y/C or analog input does not affect the safety or efficacy of the subject device because the features were taken out due to increase of digitization of external devices and the main function of the device is not changed.

• The subject device has a Peripheral device control function. The peripheral device control function is a function that allows the processor device for endoscopes to centrally control the connected peripheral devices, but since it is the same as the control that is originally performed by each peripheral device, it does not lead to any new procedures. Therefore, it is not a change that affects the safety or effectiveness of the processor device for endoscopes.

• The subject device has a Function to operate this product via a tablet with an operation extension program installed by connecting this product and a tablet. Risk analysis was performed, the addition of the tablet operation in the subject device, does not increase the safety or efficacy of the subject device.

• The subject device also has a Multi Observation option that allows endoscopic images to be displayed in the main screen area and sub-screen area by switching image processing options at every frame. This allows each image frame to be displayed in the main screen area and sub-screen area 1 with a different combination of image processing options applied [WLI+(LCI), LCI+(WLI), BLI+(WLI), WLI+(BLI)].
The effect of the image frame option is unchanged and does not affect the safety and effectiveness of the image processing option as it only switches the image processing option frame by frame on the display.

• The dimensions are modified from 390x110x485mm (for VP-7000) and 390x155x485mm BL-7000) to 395×210×515 mm. A change in the dimensions does not affect how the device is used, the difference in dimensions does not increase the safety or efficacy of the subject device.

• The weight is modified from 9kg (for VP-7000) and 12kg (BL-7000) to 18kg.The change in the device weight does not affect how the device is used, the difference in the weight does not increase the safety or efficacy of the subject device.

b. Endoscope Model EG-860R

The product code for both predicate device and subject device is FDS.

The difference in the F# of the objective lens in EG-860R 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.
Although there is a difference in the resolution of EG-860R compared to the predicate device, the resolution of EG-860R is the same as the reference devices and does not increase the safety or efficacy of the subject device.

The difference in the distal end diameter of EG-860R compared to the subject device does not affect the safety and efficacy of the subject device because this value is between Predicate and Reference devices.

The difference in the angle rubber tube material and tube material of EG-860R compared to the predicate device does not affect the safety of efficacy. Biocompatibility testing was completed, no new risks were introduced.

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

The performance of Image and the performance of the WLI, FICE, BLI, BLI-bright, LCI and ACI imaging modes available in FUJIFILM Video Processor EP-8000 was evaluated according to the engineering requirements listed in this section. The test protocols are similar to those used to evaluate the performance of the predicate devices VP-7000 and BL-7000. The engineering requirements are identical to those assessed for the predicate devices.

EP-8000 was evaluated for as follows. The image performance of EP-8000 was compared with the image performance of the predicate VP-7000 and BL-7000. Testing was conducted in combination with representative FUJIFILM gastroscopes. The following test reports are provided:
(1)color reproduction, (2)Image Geometric Distortion, (3)Image Resolution Performance, (4)Depth of field (DOF) Performance Test, (5)ISO-SNR & Dynamic Range Performance, (6)Image intensity uniformity, (7)FIELD OF VIEW (FOV). For all imaging modes, EP-8000 demonstrated substantial equivalence to VP-7000 and BL-7000 in Image performance and color reproduction. Although there are minor differences between the proposed and predicate devices, these differences do not raise new or additional questions of safety or effectiveness of the proposed devices. Thus, the proposed device EP-8000 is substantially equivalent to the predicate device.

The following performance for EG-860R was evaluated according to the engineering requirements listed in this section. The test protocols are similar to those used to evaluate the performance of the predicate devices. The engineering requirements are identical to those assessed for the predicate devices. In all cases, the devices met the pre-defined acceptance criteria for the test.
(1)Image Geometric Distortion, (2)Image Resolution Performance, (3)Depth of field (DOF) Performance Test, (4)ISO-SNR & Dynamic Range Performance, (5)Image intensity uniformity, (6)Advanced Force Transmission, (7)Adaptive Bending, (8)Field of view, (9)Bending capability, (10)Rate of suction, (11)Working length, (12)Diameter of Forceps channel, (13)Viewing direction, (14)Resolution, (15)LG output,(16)Uneven illumination, (17)Color reproducibility, (18)Air volume, (19)Water volume
Although there are minor differences between the proposed and predicate devices, these differences do not raise new or additional questions of safety or effectiveness of the proposed devices. Thus, the proposed device EG-860R is substantially equivalent to the predicate device.