July 2, 2026

Fujifilm Corporation
% Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
FUJIFILM Healthcare Americas Corporation
81 Hartwell Ave.
Suite 100
Lexington, Massachusetts 02421

Re: K261880
Trade/Device Name: FUJIFILM Processor EP-8000;Balloon Controller PB-30;Endoscopy Support Program EW10-VM01
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FET, NTN, NWB, PEA, FDF, FDA, QTH
Dated: June 5, 2026
Received: June 5, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261880

Please provide the device trade name(s).

FUJIFILM Processor EP-8000;
Balloon Controller PB-30;
Endoscopy Support Program EW10-VM01

Please provide your Indications for Use below.

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.

PB-30
This product is a balloon pump apparatus intended to inflate or deflate a balloon to assist with endoscope and over-tube insertion.
This product is not intended for use for any neonates, infants or children.

EW10-VM01
This software provides image information to assist the user in estimating the size of an object displayed in the endoscopic field of view. This software provides no therapeutic or diagnostic function.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #:

510(k) Summary

Prepared on: 2026-06-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FUJIFILM Corporation
Applicant Address	798 Miyanodai Kaise-Machi Ashigarakami-Gun Kanagawa 258-8538 Japan
Applicant Contact Telephone	704-517-4886
Applicant Contact	Ms. Chaitrali Kulkarni
Applicant Contact Email	hcusregulatoryaffairs@fujifilm.com
Correspondent Name	FUJIFILM Healthcare Americas Corporation
Correspondent Address	81 Hartwell Ave. Suite 100 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 Processor EP-8000; Balloon Controller PB-30; Endoscopy Support Program EW10-VM01
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,FDF,FDA,QTH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K243260	FUJIFILM Processor EP-8000; FUJIFILM Endoscope Model EG-860R	FET
K153483	Balloon controller PB-30	FDF
K223827	FUJIFILM Endoscope Model EC-760S-A/L, Endoscopy Support Program EW10-VM01	FDF

Device Description Summary

21 CFR 807.92(a)(4)

Processor EP-8000
A. Intended Use/indications for Use
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. Technological characteristics
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 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

C. Principles of Operation
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.

PB-30
A. Intended Use/indications for Use
This product is a balloon pump apparatus intended to inflate or deflate a balloon to assist with endoscope and over-tube insertion.
This product is not intended for use for any neonates, infants or children.

B. Technological characteristics
By connecting this product and the EN-840T double-balloon endoscope to the EP-8000 processor, the functions of the toggle switch 1, toggle switch 2 and stop switch on the PB-30 remote switch (RC-30) can be assigned to the scope switches.

C. Principles of Operation
This product activates the air feed pump unit in the main unit to feed air into the balloon attached to the ENDOSCOPE or into the balloon attached to the overtube via the solenoid valve unit and the tube kit connected to the main unit. Similarly, this product activates the air evacuation unit to evacuate air from the balloon.
By activating the solenoid valve unit, the channel between the tube kit and the air feed pump or the channel between the tube kit and the air evacuation pump is opened and closed to switch balloon air feed and balloon air evacuation. A pressure sensor located in the channel between the solenoid valve unit and the balloon monitors the air pressure inside the balloon and controls the solenoid valve unit according to the presetting pressure.
The distal end of ENDOSCOPE and the distal end of overtube can be fixed to the digestive tract by inflating the balloon at the presetting pressure.
Insertion of the ENDOSCOPE into the digestive tract is assisted by repeating air feed and air evacuation to inflate and deflate the balloon on the ENDOSCOPE side and the one on the overtube side in turn to advance the ENDOSCOPE in the body cavity.

EW10-VM01
A. Intended Use/indications for Use
This software provides image information to assist the user in estimating the size of an object displayed in the endoscopic field of view.
This software provides no therapeutic or diagnostic function.

B. Technological characteristicss
This device is used in combination with light source device, processor, medical endoscope, monitor, recording device, and peripheral device. It is an endoscopic examination supporting program for the purpose of diagnostic support. The device can be connected to EP-8000 processor / light source integrated andBL-7000 light source, VP-7000 processor. In the case of the EC-760S-A/L system endoscope, Virtual Scale display function is enabled.

C. Principles of Operation
The Personal Computer in which the endoscopy support program is installed and the processor is connected with a DVI cable and an RS-232C cable. An endoscopic movie received from an endoscope processor through a DVI cable, and a movie in which the Virtual Scale result is superimposed on the endoscopic movie is output to a monitor. The Virtual Scale display function accepts the user operation by the switch of the medical endoscope, and the operation signal is input from the endoscope processor to the endoscopic examination supporting program through the RS-232C cable.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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.

PB-30
This product is a balloon pump apparatus intended to inflate or deflate a balloon to assist with endoscope and over-tube insertion. This product is not intended for use for any neonates, infants or children.

EW10-VM01
This software provides image information to assist the user in estimating the size of an object displayed in the endoscopic field of view. This software provides no therapeutic or diagnostic function.

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)

EP-8000
This update adds the combination of the Endoscopy Support Program EW10-VM01, Expansion Unit Base Software EW10-SC01 and the balloon controller PB-30. There are no other changes to the technical specifications. We have conducted compatibility testing for this combination, and it does not affect the safety or efficacy of the proposed model.

PB-30
Change the applicable endoscopes but it was confirmed that electromagnetic compatibility with combination devices. And Change the applicable over-tubes but it has been tested in combination with theTS-1314B. Change the combination with connecting tubes, but it has been tested in combination with the TY-500D.
As for these changes of the combinations, this device and combination devices were confirmed that as intended to can be operated safely based on the above standards.
Software Update but his it was confirmed that as intended to can be operated safely based on software test.

EW10-VM01
EP-8000 add the combination of processor but combination verification was conducted on the additional equipment, and it was confirmed that there was no impact on the intended functions, performance, safety, efficacy, etc. of this software.
Add the supports OS but the design verification was conducted in the operating environment to be added, and it was confirmed that there was no impact on the intended functions, performance, safety, effectiveness, etc. of this software.

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

This update adds the combination of the endoscope support program EW10-VM01and the PB-30 balloon controller PB-30. There are no other changes to the technical specifications. We have conducted compatibility testing for this combination, and it does not affect the safety or efficacy of the proposed model.