June 13, 2025

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

Re: K244017
Trade/Device Name: FUJIFILM Endoscope Model EB-710P; FUJIFILM Processor EP-8000
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: May 16, 2025
Received: May 16, 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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*

K244017

Device Name

FUJIFILM Endoscope Model EB-710P;
FUJIFILM Processor EP-8000

Indications for Use *(Describe)*

a. Endoscope Model EB-710P
Endoscope Model EB-710P is a bronchoscope intended for the observation, diagnosis and endoscopic treatment of the trachea and bronchus at medical facilities under the management of physicians. Never use this product for any other purposes.

b. 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 is used for endoscopic observation, diagnosis and treatment.

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) #: K244017

510(k) Summary

Prepared on: 2025-06-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FUJIFILM Corporation
Applicant Address	798 Miyanodai Kaisei-MachiI Ashigara Kami-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 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 EB-710P; FUJIFILM Processor EP-8000
Common Name	Bronchoscope (flexible or rigid) and accessories
Classification Name	Bronchoscope (Flexible Or Rigid)
Regulation Number	874.4680
Product Code(s)	EOQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220957	FUJIFILM Endoscope Model EB-710P	EOQ
K163675	Processor VP-7000, Light Source BL-7000	FET

Device Description Summary

21 CFR 807.92(a)(4)

A. Intended Use/indications for Use

a. Endoscope Model EB-710P

FUJIFILM Endoscope Model EB-710P is a bronchoscope intended for the observation, diagnosis and endoscopic treatment of the trachea and bronchus at medical facilities under the management of physicians.

b. 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 is used for endoscopic observation, diagnosis and treatment.

B. Technological characteristics
a. Endoscope Model EB-710P
FUJIFILM Endoscope Model EB-710P is comprised of three general sections: an insertion portion, a control portion, and a connector portion to the peripherals. The insertion portion is flexible and contains glass fiber bundles, several channels, and a complementary metal-oxide semiconductor (CMOS) image sensor in its distal end. 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 CMOS image sensor to capture an image and display it on the monitor. The channels in the insertion portion assist in delivering suction as well as endoscopic accessories. The control portion controls the angulation and rotation of the bending portion in the insertion portion. The connector portion consists of electronic components needed to operate the endoscope when connected to the video processor. The endoscopes are used in combination with FUJIFILM's video processors, light sources, and peripheral devices such as monitor, printer, foot switch, and cart.

b. 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 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
a. Endoscope Model EB-710P
The proposed device function on the same principles of operation as the predicate device, EB-710P (K220957). They are bronchoscopes that can be inserted trans-nasally or perorally into the trachea and bronchial tree for observation, diagnosis, and treatment of these regions. After connecting to the light source and video processor, the devices guide the light through the fiber bundles situated inside the insertion portion of the devices. 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 devices. The video processor converts the electric signal into a video signal and displays an image on a monitor. This image is used for the visualization of the trachea and bronchial tree.

b. 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

a. Endoscope Model EB-710P
Endoscope Model EB-710P is a bronchoscope intended for the observation, diagnosis and endoscopic treatment of the trachea and bronchus at medical facilities under the management of physicians. Never use this product for any other purposes.

b. 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 is used for endoscopic observation, diagnosis and treatment.

Indications for Use Comparison 21 CFR 807.92(a)(5)

a. Endoscope Model EB-710P
The indication for use for the proposed device and the predicate devices are same.

b. 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).

Technological Comparison 21 CFR 807.92(a)(6)

a. Endoscope Model EB-710P
The product code for both predicate device and subject device is EOQ.
The EP-8000 processor has been added as a new option, but there are no other changes to the accessories.
With the addition of the EP-8000, there are no differences in the functionality, performance, or safety of the predicate device and the subject device in endoscopy.

b. 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 effectiveness of the subject device compared to the predicate device.

• Product CODE changed from FET, NTN, NWB, PEA to EOQ. The addition of EOQ product code does not change the intended use of the device compared to the predicate device. The EOQ for the VP-7000 and BL-7000 has been added in K220957.

• 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 impact the safety or effectiveness.

• The subject device is compatible with the following.
700 System endoscopies (710series),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.

• 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 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 effectiveness of the subject device.

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.

Software specific testing was conducted using the following consensus standard: IEC 62304:2015. The software validation activities were performed in accordance with the FDA Guidance, Content of Premarket Submissions for Device Software Functions, issued on June 14, 2023.

Color and optical performance in endoscopic systems is affected by the characteristics of the light source mounted by the processor and the image sensor carried by the endoscope. The predicate device VP-7000/BL-7000 and the subject device EP-8000 are equipped with identical LED lamps for all four colours: violet, blue, green and amber. This causes no difference in color performance.

Bench testing of the performance of the WLI image modes available on the EP-8000 were conducted on representative models from bronchoscopes, demonstrating that the subject devices are substantially equivalent in performance to the predicate devices.

The performance of Image and the performance of the WLI imaging mode 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 bronchoscopes (EB-710P:K220957). 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.