June 16, 2026

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

Re: K253137
Trade/Device Name: FUJIFILM Endoscope Model EB-840S; FUJIFILM Endoscope Model EB-840T
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: May 15, 2026
Received: May 15, 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,

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.

510(k) Number *(if known)*
K253137

Device Name
FUJIFILM Endoscope Model EB-840S;
FUJIFILM Endoscope Model EB-840T

Indications for Use *(Describe)*
This product is a bronchoscope intended for the observation, diagnosis and endoscopic treatment of the trachea and bronchus at medical facilities under the management of physicians.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K253137

510(k) Summary

Prepared on: 2026-06-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FUJIFILM Corporation
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Applicant Contact	Ms. Chaitrali Kulkarni
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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-840S; FUJIFILM Endoscope Model EB-840T
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
K183607	FUJIFILM Endoscope Model EB-580S	EOQ

Device Description Summary

21 CFR 807.92(a)(4)

A. Intended Use/indications for Use

This product 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. Technological characteristics

This product consists of an endoscope and standard accessories. The endoscope consists of an insertion portion (which consists of a

distal end, a bending section and a flexible portion), a control portion, an LG flexible portion and a scope connector.
This product is medical electronic endoscope for bronchus, and it is inserted into the lumen, coelom, body cavity, or inside of the body, which provides images for observation, diagnosis, photographing, or treatment.
This product is a bronchoscope intended for the observation, diagnosis and endoscopic treatment of the trachea and bronchus at medical facilities under the management of physicians.

C. Principles of Operation

Connecting the light source, this product guides the light from it through the bundled fiber placed and set inside this product. This product emit light from the tip of the insertion portion. Its reflection forms an image on CMOS image sensor through a group of object lens placed and set in the tip of t his product. An electric signal from CMOS image sensor is transmitted to the processor via the light source connected to this product. The processor converts it to a video signal and displays an image on a monitor.
Insertion portion of the devices have a mechanism (hereinafter "the bending section") which bends the tip from up and down, a flexible tube (hereinafter "the insertion tube") consists of the bending section and operating portion with a lever which controls the bending section. And these devices have a mechanism (hereinafter "the rotation mechanism") which rotate the insertion portion with a rotation ring.
In the suction channel, air is constantly suctioned by the suction unit. Pressing the suction valve enables suction to be performed from the forceps channel.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This product is a bronchoscope intended for the observation, diagnosis and endoscopic treatment of the trachea and bronchus at medical facilities under the management of physicians.

Indications for Use Comparison

21 CFR 807.92(a)(5)

There is slight difference in the description of the predicate device compared to a bronchoscope, the subject device is intended for the trachea and bronchus where as the predicate device is intended for trachea and bronchial tree. The difference between the intended use of the subject device and the predicate device does not raise any new questions of safety or efficacy.

Technological Comparison

21 CFR 807.92(a)(6)

(A) EB-840S
The subject device EB-840S and predicate device EB-580S share the same Viewing direction, observation range, Field of View, and F number of the objective lens.

The resolution at near side of the subject device is same as the reference device EB-710P, and far side is same as the predicate device EB-580S.

The subject device has a different integrated image sensor then the predicate, however the subject device integrated image sensor is same as reference device.

The number of light guide fiber bundles of the subject device is between the predicate device and reference device. This difference between the light guide fiber bundles from the subject device and predicate device does not affect the safety or efficacy of the subject device.

The flexible portion diameter, maximum insertion diameter, bending capability, forceps channel diameter, and working length are the same for the subject device and the predicate device.
The distal end diameter is not same as predicate device, but it is between predicate and reference device.
The insertion portion rotation function, rotation range, total length, connection portion, power supply method for connector and CPU/ Software is not same as predicate device, but it is same as reference device EB-710P.

(B) EB-840T
The subject device EB-840T and predicate device EB-580S share the same Viewing direction, observation range, Field of View, and F number of the objective lens.

The resolution at near side of the subject device is same as the reference device EB-710P, and far side is same as the predicate device EB-580S.

The subject device has a different integrated image sensor then the predicate, however the subject device integrated image sensor is same as reference device.

The number of light guide fiber bundles of the subject device is between the predicate device and reference device. This difference between the light guide fiber bundles from the subject device and predicate device does not affect the safety or efficacy of the subject device.

The distal end diameter, flexible portion diameter and maximum insertion diameter is not same as predicate device but is between predicate and reference device.
The working length is same as predicate device.
The bending capability is the same for the predicate device and reference device EB-580T.
The Forceps channel is not same as predicate device but is same as reference device EB-580T.
The insertion portion rotation function, rotation range, total length, connection portion, power supply method for connector and CPU/ Software is not same as predicate device, but it is same as reference device EB-710P.

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

The following performance for the subject device was evaluated according to the engineering requirements listed in this section. In all cases, the devices met the pre-defined acceptance criteria for the test.

(1)Field of view, (2)Bendng capability, (3)Rate of suction, (4)Working length, (5)Diameter of forceps channel, (6)Viewing direction, (7)Resolution, (8) LG output, (9) Uneven illumination, (10)Color reproducibility

Although there are minor differences between the subject device and predicate devices, these differences do not raise new or additional questions of safety or effectiveness of the subject devices. Thus, the subject device is substantially equivalent to the predicate device.