



December 12, 2025

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

Re: K250863

Trade/Device Name: FUJIFILM Ultrasonic Endoscope EB-710US
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ, ITX, PSV
Dated: November 12, 2025
Received: November 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,

Joyce C. Lin -S

for 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

Indications for Use

Submission Number (if known)

K250863

Device Name

FUJIFILM Ultrasonic Endoscope EB-710US

Indications for Use (Describe)

This product is an ultrasonic endoscope intended for the observation, diagnosis and endoscopic treatment of the esophagus, trachea, bronchus and lesions adjacent to these structures using ultrasonic images, at medical facilities under the management of physicians.

This product is not intended for use on children and infants.

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.

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	FUJIFILM Ultrasonic Endoscope EB-710US
Common Name	Bronchoscope (flexible or rigid) and accessories
Classification Name	Bronchoscope (Flexible Or Rigid)
Regulation Number	874 4680
Product Code(s)	EOQ, ITX, PSV

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K121035	FUJINON/FUJIFILM ULTRASONIC ENDOSCOPE EB-530US	EOQ
K183525	EVIS EUS Ultrasound Bronchofibervideoscope Olympus BF-UC190F	PSV
K220957	FUJIFILM Endoscope Model EB-710P	EOQ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

A. Intended Use/indications for Use

This product is an ultrasonic endoscope intended for the observation, diagnosis and endoscopic treatment of the esophagus, trachea, bronchus and lesions adjacent to these structures using ultrasonic images, at medical facilities under the management of physicians. This product is not intended for use on children and infants.

B. Technological Characteristics

EB-710US (referred to as 'the device') is a medical ultrasonic electronic endoscope. The device is inserted into a lumen, a coelom, body cavity, or inside of a body, and provides images for observation, diagnosis, photographing, or treatment. It is also used for ultrasonography by visualizing the shape, the characteristic, or the dynamics of the inside of the body.

This product 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, a channel, a complementary metal-oxide semiconductor (CMOS) image sensor and a ultrasonic transducer 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 channel in the insertion portion assist in delivering suction as well as endoscopic accessories. The control portion controls the angulation 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.

This product is used in combination with FUJIFILM's video processors, light sources, and peripheral devices such as monitor, printer, foot switch, and cart. And the device drives ultrasonic transducer installed in the distal end of the device by being connected with a ultrasonic processor.

The driven ultrasonic transducer emits ultrasound into the body, and receives the reflected ultrasonic signal from the body. The ultrasonic processor connected to the device performs image processing using the received signal. The electric signal of the image processing is converted into video signal, and it is output to the monitor as a ultrasonic image.

C. Principles of Operation

The device is connected to a light source, and provides illumination from the distal end of the device by guiding lights with optical fiber bundles installed in the device. The reflected light provides an image on CMOS through objective lens installed in the distal end of the device. The CMOS signal is transmitted to a processor connected to the device. The processor converts the electric signal to the image signal, and it is viewed on a monitor.

The device drives ultrasonic transducer installed in the distal end of the device by being connected with an ultrasonic processor. The driven ultrasonic transducer emits ultrasound into the body, and receives the reflected ultrasonic signal from the body. The ultrasonic processor connected to the device performs image processing using the received signal. The electric signal of the image processing is converted into video signal, and it is output to the monitor as an ultrasonic image. The ultrasonic image is obtained by contact method.

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. The instrument channel which runs through the operating portion to the tip is arranged inside the insertion portion for inserting the endotherapy device under endoscopic observation and needle aspiration by ultrasound aspiration needle under ultrasonic observation.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

This product is an ultrasonic endoscope intended for the observation, diagnosis and endoscopic treatment of the esophagus, trachea, bronchus and lesions adjacent to these structures using ultrasonic images, at medical facilities under the management of physicians. This product is not intended for use on children and infants.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The predicate has a difference in the site of application. However, the Olympus Model BF-UC190F bronchoscope, which is used as the reference, includes the esophagus. As the intended use is similar and it is a model that has already been marketed, it is judged that adding the esophagus will not cause any problems with safety or efficacy.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The ultrasound specification of the proposed device are similar to the predicate devices; there are no new concerns for safety or efficacy.

Although there are differences in the proposed device in the CMOS image sensor, objective optical system, illumination optical system, light fiber guide, endoscope image design, image processing algorithms, and software when compared to the predicate device; the technological differences between the proposed device and the predicate device do not raise any new questions of safety or efficacy. Additionally the listed specifications are similar to the reference device, EB-710P (K220957).

Proposed device model EB-710US has difference in Maximum insertion diameter, Forceps channel diameter, Power supply method for connector and Communication method for connector when compared to the predicate device, but the difference in the specifications do not raise any new questions of safety or efficacy.

As the difference of Distal end diameter, Flexible portion diameter, Bending capability UP and Total length is between the specifications

of the predicate and reference models, there are no new concerns for safety or efficacy.

The accessories used in the proposed device are comparable to the predicate device. All accessories were tested to ensure they are compatible with the device, there are no new concerns for safety or efficacy.

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

The proposed device and the predicate device have a difference in the below listed specifications. All specifications were tested with a pre-defined acceptance criteria and all specifications passed the testing requirements. There are no new concerns for safety or efficacy.

(1) Field of view, (2) Bending 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 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 is substantially equivalent to the predicate device.