February 7, 2024

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

Re: K240075
Trade/Device Name: FUJIFILM Endoscope Model EB-710XT
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: January 10, 2024
Received: January 10, 2024

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.

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

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)*

K240075

Device Name

FUJIFILM Endoscope Model EB-710XT

Indications for Use *(Describe)*

Endoscope Model EB-710XT 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.

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.

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510(k) Summary

Prepared on: 2024-01-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Fujifilm Healthcare Americas Corporation
Applicant Address	81 Hartwell ave suite 300 Lexington MA 02421 United States
Applicant Contact Telephone	704-517-4886
Applicant Contact	Ms. Chaitrali Kulkarni
Applicant Contact Email	chaitrali.kulkarni@fujifilm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	FUJI FILM Endoscope Model EB-710XT
Common Name	Bronchoscope (flexible or rigid) and accessories
Classification Name	Bronchoscope (Flexible Or Rigid)
Regulation Number	874.4680
Product Code	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

Device Description Summary

21 CFR 807.92(a)(4)

A. Intended Use/indications for Use

Endoscope Model EB-710XT 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. Technological Characteristics

The proposed device consists of a non-insertion portion and an insertion portion. The insertion portion is inserted trans-nasally or perorally into the trachea and bronchial tree during clinical use.

The insertion portion is flexible and consists of the bending section (hereinafter "bending portion") and the insertion tube (hereinafter "flexible portion"). The bending portion features a mechanism that bends the tip up and down. The insertion portion can also be rotated so that the distal end of the endoscope is steered to the anatomic region of interest. 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, Instrument channel outlet, Objective lens, and Light guide.

The bending portion is controlled by lever on the control portion/operation section to angulate the distal end to certain angles.

The flexible portion contains light guides (glass fiber bundles), an instrument/suction channel, a complementary metal-oxide

semiconductor (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 control portion provides a grip on the endoscopes and contains mechanical parts to operate the endoscopes. The control portion features an angle lever and a rotation ring which control the angulation and the rotation of the distal end. The instrument/suction channel runs through the control portion and the insertion portion for introducing the endoscopic accessories or electrosurgical instrument, as well as providing suction.

C. Principles of Operation
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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Endoscope Model EB-710XT 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use of the subject device and the predicate device (K220957) are the same.

Technological Comparison

21 CFR 807.92(a)(6)

There is a difference in the sizes of the distal end diameter, flexible portion diameter, forcep channel diameter, and maximum insertion diameter in comparison to the predicate device. Although the sizes are larger then the predicate device, the sizes of the distal end diameter, flexible portion diameter, forcep channel diameter, and maximum insertion diameter are smaller than the reference device (EVIS EXERA III Bronchovideoscope Olympus BF-XT190, K183419), therefore there are no new concerns for safety or effectiveness.

The Bending Capability Up is different than the predicate device, however the subject device has a smaller degree of bending than the predicate device, therefore there is no new concern for safety and effectiveness.

Some parts of the device have a different material used in the subject device compared to the predicate device, however the material used is used other other parts of the predicate device, therefore there is no new concern for safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The changes to the proposed device models are in the dimensions as distal end diameter, flexible portion diameter, forceps channel diameter, and maximum insertion diameter, and the down bending capability. To determine if the changes would affect the safety or efficacy of the subject device, performance testing was conducted, and the subject device passed all test objectives. It was determined that the new endoscope models are substantially equivalent to the predicate device.

Endoscope specific testing was conducted according to ISO 8600-1: 2015
The proposed device met performance specifications in the following additional testing:
- Field of view
- Bending capability
- Working length
- Diameter of forceps channel
- Viewing direction
- Resolution
- LG output