November 10, 2022

FUJIFILM Corporaton
% Kotei Aoki
Senior Regulatory Affairs Specialist
FUJIFILM Healthcare Americas Corporation
81 Hartwell Avenue, Suite 300
Lexington, Massachusetts 02421

Re: K220957
Trade/Device Name: FUJIFILM Endoscope Model EB-710P
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: October 13, 2022
Received: October 13, 2022

Dear Kotei Aoki:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220957

Device Name
FUJIFILM Endoscope Model EB-710P

Indications for Use *(Describe)*
FUJIFILM Endoscope Model EB-71 OP 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

FUJIFILM Corporation

FUJIFILM Endoscope Model EB-710P

Date: March 31, 2022

Submitter's Information:
FUJIFILM Corporation
798 MIYANODAI KAISEI-MACHI
ASHIGARAKAMI-GUN, KANAGAWA
258-8538 JAPAN

Contact Person:
Kotei Aoki
Senior Regulatory Affairs Specialist
E-Mail: kotei.aoki@fujifilm.com
Telephone: (765) 246-2931

Identification of the Proposed Device:

Device Name:	FUJIFILM Endoscope Model EB-710P
Common Name:	Bronchoscope
Product Code:	EOQ
Device Class:	Class 2
Regulation Number:	874.4680
Regulation Description:	Bronchoscope
Review Panel:	Ear Nose & Throat

Predicate Device:

- FUJIFILM Endoscope Model EB-580S (K183607)

Reference Devices:

- FUJIFILM Endoscope Model EC-760S-V/L (K190649)
- OLYMPUS Endoscope Model BF-P190 (K201758)

Intended Use / Indications for Use:

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.

Never use this product for any other purposes.

Device Description:

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.

Comparison of Technological Characteristics:

The comparison is summarized in the tabular format in Tables below.

Table 1

		Proposed Device FUJIFILM Endoscope Model EB-710P (to be assigned)	**Predicate Device FUJIFILM Endoscope Model EB-580S (K183607)**	**Reference Device 1 FUJIFILM Endoscope Model EC-760S-V/L (K190649)**	**Reference Device 2 OLYMPUS Endoscope Model BF-P190 (K201758)**
Indications for Use (IFU)		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. Never use this product for any other purposes.	The device is intended for the observation, diagnosis, and endoscopic treatment of trachea and bronchial tree.		
Viewing direction		Forward / 0°			
Observation range		2mm - 50mm	2mm - 100mm		2mm - 50mm
Acceptance Criteria of Resolution		At 2mm of working distance:0.08mm of line pair on the square wave chart is readable. At 50mm of working distance:1.25mm of line pair on the square wave chart is readable.	At 4mm of working distance: 0.1mm of line pair on the square wave chart is readable. At 100mm of working distance: 1.6mm of line pair on the square wave chart is readable.		
Field of View		120°			
Bending capability	Vertical	Up 210° / Down 130°			
	Horizontal	Right N/A / Left N/A			
Rotation capability (Insertion portion)		Right:120° / Left:120°	N/A		Right:120° / Left:120°
Image sensors		CMOS	CCD	CMOS	
Distal end diameter		4.1mm	5.3mm		4.2mm
Flexible portion diameter		4.1mm	5.1mm		4.1mm
Maximum insertion diameter		4.9mm	6.5mm		
Forceps channel diameter		2.0mm	2.2mm		2.0mm
Working length		600mm			
Total length		880mm	870mm		880mm
Connector (communication		Scope Connector	LG connector/Video connector	Scope Connector	

method)	(optical communication)	(electrical contact)	(optical communication)	
Connector power supply method	electromagnetic induction (non-electrical contact)	electrical contact	electromagnetic induction (non-electrical contact)	
Connector CPU/Software	Installed	N/A	Installed	
Standard Accessories	Suction Channel Brush (WB7025DC)			
	Cylinder/Inlet Brush (WB11003DV)			
	Suction Valve (SB-607)	Suction button (SB-500B/D)		
	Forceps Valve (FOV-BU1)	Forceps Valve (FOV-DV7)		
	Cleaning Adapter (CA-616)	Cleaning Adapter Kit (CA-500C)		
	Ventilation Adapter (AD-7)			
Optional Accessories	Air leak tester (LT-7F)			
	Suction Valve (SB-606)	Suction Valve (SB-602)		
	Forceps Valve (FV-003)			
Light Source/Video Processor	BL-7000/VP-7000	XL-4450/VP-4440HD EPX-3500HD BL-7000/VP-7000 EP-6000	BL-7000/VP-7000	
Peripherals	Endoscopic Accessories			
	Electrosurgical Instruments			
Control Portion	New control portion	G5 control portion		
STERRAD Sterilization	Yes	No		

Performance Data:

Validation of the cleaning, disinfection, and sterilization instructions was performed in accordance with FDA's guidance, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, published March 17, 2015.

Biocompatibility of the proposed device was evaluated using the following consensus standards: ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-10:2010. Biocompatibility testing was conducted in accordance with the FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process",* issued September 4, 2020.

Software of the proposed device was evaluated in accordance with IEC 62304:2006 and the FDA guidance, *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices*, issued May 11, 2005, and, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued October 2, 2014.

Electrical safety and EMC of the proposed device was evaluated using following standards: ANSI/AAMI ES 60601-1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010/AMD1:2013, and IEC 60601-2-18:2009

Laser safety and photobiological safety of the proposed device was evaluated using the following standards: IEC 60825-1:2007 and IEC 62471:2006.

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
- Rate of suction
- Working length
- Diameter of forceps channel
- Viewing direction
- Resolution
- LG output

Optical and color performance of the proposed device was evaluated. In all cases, the proposed device demonstrated substantial equivalence to the predicate device.

Conclusions:

The proposed device FUJIFILM Endoscope Model EB-710P shares the same intended use and indications for use as, similar technological characteristics to, the same principles of operation as, and similar materials to the predicate device and the reference devices. The remaining differences in EB-710P, compared to the predicate device, have either 1) been cleared in the reference devices or 2) been evaluated for the biocompatibility, the electrical safety, the EMC testing, and the bench testing. The testing demonstrates that the proposed device remains as safe and effective as the predicate device and there is no new concern regarding the safety and effectiveness. FUJIFILM Endoscope Model EB-710P is substantially equivalent to the predicate device, FUJIFILM Endoscope Model EB-580S (K183607).