January 19, 2018

FUJIFILM Medical Systems U.S.A., Inc.
Jeffrey Wan
Specialist, Regulatory Affairs
10 High Point Drive
Wayne, NJ 07470

Re: K171291
Trade/Device Name: FUJIFILM Bronchoscope Model EB-530P
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: December 18, 2017
Received: December 19, 2017

Dear Jeffrey Wan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eric A. Mann -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171291

Device Name
FUJIFILM Bronchoscope Model EB-530P

Indications for Use *(Describe)*
The FUJIFILM Bronchoscope Model EB-530P is intended for the observation, diagnosis, and endoscopic treatment of the trachea and bronchial tree.

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 Medical Systems U.S.A., Inc.'s

FUJIFILM Bronchoscope Model EB-530P

Date: January 15, 2018

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.,
Endoscopy Division
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Person:

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Specialist, Regulatory Affairs
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Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM Bronchoscope Model EB-530P
Common Name:	Bronchoscope
Device Class:	Class II
Review Panel:	Ear, Nose, and Throat

Classification Information:

Classification Name	CFR Section	Product Codes
Bronchoscope (flexible or rigid) and accessories	21 CFR 874.4680	EOQ

Predicate Devices

- Fujinon/Fujifilm EB-530 Series Bronchoscopes Model EB-530S (K122535)

Intended Use / Indications for Use

The FUJIFILM Bronchoscope Model EB-530P is intended for the observation, diagnosis, and endoscopic treatment of the trachea and bronchial tree.

Device Description

The FUJIFILM Bronchoscope Model EB-530P is comprised of three general sections: a control/ operating section, an insertion portion and an umbilicus. The control/operating section controls the angulation (up/down) of the distal end of the endoscope. The insertion portion contains glass fiber bundles, several channels and a complementary charged coupled device (CCD) image sensor in its distal end. The channels in the insertion portion assist in delivering air/suction as well as endoscope accessories, such as forceps. 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 CCD image sensor to capture an image and display it on the monitor. The umbilicus consists of electronic components needed to operate the endoscope when plugged in to the video processor and the light source.

The subject device is used in combination with FUJIFILM's video processors, light sources and peripheral devices such as monitor, printer, foot switch, and cart. All of these combinations were previously cleared in K122535.

Technological Characteristics

A comparison of the technological characteristics between the subject and predicate devices is provided in the **Table 7-1** below.

Performance Data

Electrical safety of the subject device was evaluated using following standards: ANSI/AAMI ES 60601-1:2012, IEC 60601-1-2:2007, IEC 60601-1-6:2013, and IEC 60601-2-18:2009.

Biocompatibility of the subject devices was evaluated using the following consensus standards: ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

Cleaning, high-level disinfection, and EO sterilization validation were performed to validate the reprocessing instructions recommended in the labeling.

Endoscope specific testing was conducted using the following consensus standards: ISO 8600-1:2015, ISO 8600-3:1997, and ISO 8600-4:2014.

Subject devices met performance specifications in the following additional testing:

- Field of view
- Bending capability
- Rate of suction
- Working length
- Dianeter of forceps channel
- Viewing direction
- LG Output

Table 7.1: Comparison of FUJIFILM Bronchoscope Model EB-530P with its predicate device Fujinon/Fujifilm EB-530 Series Bronchoscope Model EB-530S (K122535)

		Predicate Device Fujinon/Fujifilm EB-530 Series Bronchoscopes Model EB-530S (K122535)	Proposed Device FUJIFILM Bronchoscope Model EB-530P
Device Name		FUJIFILM Video Bronchoscope	FUJIFILM Video Bronchoscope
		EB-530S	EB-530P
510(k) Number		K122535	K171291
Indications for Use (IFU)		The device is intended for the observation, diagnosis, and endoscopic treatment of trachea and bronchial tree.	Same as predicate device
Viewing direction		Forward/ 0 degree	Same as predicate device
Observation range		3mm - 100mm	Same as predicate device
Field of View		120 degrees	Same as predicate device
Distortion characteristics		Orthogonal Projection	Same as predicate device
Image sensors		CCD	Same as predicate device
Distal end diameter		**4.9mm**	**3.8mm**
Flexible portion diameter		**4.9mm**	**3.8mm**
Maximum insertion diameter		**5.9mm**	**4.2mm**
Bending capability	Up	180 degrees	Same as predicate device
	Down	130 degrees	Same as predicate device
Forceps channel diameter		**2.0mm**	**1.2mm**
Working length		600mm	Same as predicate device
Total length		**870mm**	**890mm**
Video Processor		**EPX-2500** **EPX-4400** **EPX-4400HD** **EPX-4440HD**	**EPX-4440HD**

	Predicate Device **Fujinon/Fujifilm EB-530 Series** **Bronchoscopes Model EB-530S (K122535)**	**Proposed Device** **FUJIFILM Bronchoscope Model EB-530P**
Peripherals	**Endoscopic Accessory (i.e. Forceps)**	**Endoscopic accessory i.e. forceps caliber under φ1.2mm**
	Monitor	Same as predicate device
	Printer	Same as predicate device
	Electrosurgical Instruments	**N/A**
Peripherals	Foot Switch	Same as predicate device
	Cart	Same as predicate device
Standard Accessories	Channel Cleaning brush **WB3212FW2** WB3503FW	Channel Cleaning Brush **WB2212FW2** WB3503FW
	Valve Cleaning brush (WB11002FW2)	Same as predicate device
	Cleaning Adapter Kit (CA-500C)	Same as predicate device
	Forceps Valve (FOV-DV7)	Same as predicate device
	Suction button (SB-500B/D)	Same as predicate device
	Ventilation Adapter (AD-7)	Same as predicate device
Optional Accessories	Air leak tester LT-7F	Same as predicate device
	Sterile Suction button (SB-602)	Same as predicate device

Substantial Equivalence

FUJIFILM Bronchoscope Model EB-530P has the same intended use and indications for use, as well as similar technological characteristics and principles of operation as its predicate device Fujinon/Fujifilm EB-530 Series Bronchoscopes Model EB-530S (K122535). The modifications done to the subject device include changes in number of light guide fiber bundles, dimensions, accessories, transport and storage conditions, and materials.

These minor dimensional and material differences between the FUJIFILM Bronchoscope Model EB-530P and its predicate device Fujinon/Fujifilm EB-530 Series Bronchoscopes Model EB-530S were made for the purpose of overall product enhancement and general technological advancement, and raise no new issues of safety or effectiveness. The material changes in the subject device do not raise new concerns regarding biocompatibility as discussed in section XVII. Performance data demonstrated that the FUJIFILM Bronchoscope Model EB-530P has substantially equivalent performance to the predicate device Fujinon/Fujifilm EB-530 Series Bronchoscopes Model EB-530S (K122535). The subject device is successfully validated for the electrical safety and reprocessing instructions, supporting their safety equivalent to the predicate device.

Conclusions

The subject device, Bronchoscope Model EB-530P is substantially equivalent to its predicate device Fujinon/Fujifilm EB-530 Series Bronchoscopes Model EB-530S (K122535), based on the same intended use/indications for use and similar technological characteristics. The differences in the dimensions and materials between the subject device and its predicate device raise no new issues of safety or effectiveness. Bench testing data demonstrated that the subject device has substantially equivalent performance to the predicate. Thus, the subject device FUJIFILM Bronchoscope Model EB-530P is substantially equivalent to its predicate device Fujinon/Fujifilm EB-530 Series Bronchoscopes Model EB-530S (K122535).