August 23, 2019

FUJIFILM Corporation
% Jeffrey Wan
Specialist, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K183607
Trade/Device Name: FUJIFILM Bronchoscope
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: July 24, 2019
Received: July 25, 2019

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. 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,

for Srinivas Nandkumar, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183607

Device Name

FUJIFILM Bronchoscopes EB-580S and EB-580T

Indications for Use *(Describe)*

FUJIFILM Bronchoscopes EB-580S and EB-580T are 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 Corporation's
FUJIFILM Bronchoscopes EB-580S and EB-580T

Date: August 14, 2019

Submitter's Information:

FUJIFILM Corporation
798 Miyanodai Kaisei-Machi
Ashigarakami-Gun, Kanagawa, 258-8538, Japan
FDA Establishment Registration Number: 3001722928

Contact Person:

Jeffrey Wan
Specialist, Regulatory Affairs
Telephone: (201) 675-8947
E-Mail: jeffrey.wan@fujifilm.com

Identification of the Proposed Devices:

Proprietary/Trade Name:	FUJIFILM Bronchoscopes EB-580S and EB-580T
Common Name:	Bronchoscope
Device Class:	Class II
Review Panel:	Ear, Nose & Throat

Classification Information:

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

Predicate Devices:

- FUJIFILM Video Bronchoscopes EB-530S and EB-530T (K122535)

Intended Use / Indications for Use

FUJIFILM Bronchoscopes EB-580S and EB-580T are intended for the observation, diagnosis, and endoscopic treatment of the trachea and bronchial tree.

Device Description

FUJIFILM Bronchoscopes EB-580S and EB-580T are comprised of three general sections: a control portion, an insertion portion and an umbilicus. The control portion controls the angulation of the endoscope. This portion also controls the flexibility of the distal end in the endoscope. The insertion portion contains glass fiber bundles, several channels and a charge-coupled device (CCD) image sensor in its distal end. The channels in the insertion portion assist in delivering 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 into the video processor and light source. The endoscopes are 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.

EB-580S and EB-580T can be used with Video Processor VP-7000 and Light Source BL-7000. However, LCI, FICE, and BLI imaging modes are not compatible with the subject devices.

Comparison of Technological Characteristics

FUJIFILM Bronchoscopes EB-580S and EB-580T differ from the predicate devices EB-530S and EB-530T in terms of technological characteristics and materials. The subject and predicate devices share the same mode of operation and intended use.

A summary of major differences between the subject devices EB-580S and EB-580T and the predicate devices EB-530S and EB-530T is provided as follows:

- The subject devices are compatible with Video Processor VP-7000 and Light Source BL-7000 (K163675).
- The subject devices are compatible with the disposable cleaning brushes WB11003DV and WB7025DC
- The epoxy resin used in both insertion and non-insertion portions of the subject devices has been modified.

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 device was evaluated using the following consensus standards: ISO 10993-1:2009, 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 June 16, 2016.

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

Cleaning, high-level disinfection, and sterilization of the subject device were evaluated according to the following consensus standards: AAMI TIR12:2010, AAMI TIR30:2011. 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.

The subject 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

Substantial Equivalence

The subject devices FUJIFILM Bronchoscopes EB-580S and EB-580T are substantially equivalent to the predicate devices, FUJIFILM Video Bronchoscopes EB-530S and EB-530T (K122535). The subject devices have the same intended use/indications for use and substantially similar technological characteristics and principles of operation as that of the predicate devices. Material changes to the predicate devices have been validated through biocompatibility testing. Thus, the subject devices FUJIFILM Bronchoscopes EB-580S and EB-580T are substantially equivalent to the predicate devices.

Conclusions

The subject devices FUJIFILM Bronchoscopes EB-580S and EB-580T are substantially equivalent to the predicate devices based on the same intended use, indications for use, similar technological characteristics and materials. The differences in technological characteristics and materials between the subject and predicate devices raise no new issues of safety or effectiveness. Bench testing data demonstrated that the subject devices are substantially equivalent in performance to the predicate devices. The difference in materials between subject and predicate devices has been validated through biocompatibility testing. Thus, the subject devices FUJIFILM Bronchoscopes EB-580S and EB-580T are substantially equivalent to the predicate devices, FUJIFILM Video Bronchoscopes EB-530S and EB-530T (K122535).