February 22, 2019

FUJIFILM Corporation
% Jeffrey Wan
Specialist, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
419 West Ave.
Stamford, Connecticut 06902

Re: K182825
Trade/Device Name: FUJIFILM Ultrasonic Endoscope
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ, ITX
Dated: January 22, 2019
Received: January 23, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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 yours,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number *(if known)*

K182825

Device Name

FUJIFILM Ultrasonic Endoscope EB-530US

Indications for Use *(Describe)*

EB-530US is intended for the observation, diagnosis, and endoscopic treatment of the trachea, bronchial tree and surrounding organs using ultrasonic images. It is used with a FUJIFILM ultrasonic processor, video processor, light source, other peripheral equipment and endoscopic accessories. It 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

FUJIFILM Ultrasonic Endoscope EB-530US

Date: October 3, 2018

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 Device:

Proprietary/Trade Name:	FUJIFILM Ultrasonic Endoscope EB-530US
Common Name:	Ultrasonic Endoscope
Device Class:	Class II
Review Panel:	Ear, Nose & Throat
Classification:	Bronchoscope and accessories, 21 C.F.R. § 874.4680 Diagnostic ultrasonic transducer, 21 C.F.R. § 892.1570
Product Code:	EOQ, ITX

Predicate Device:

Fujifilm Ultrasonic Endoscope EB-530US (K121035)

Reference Device:

Fujifilm Video Colonoscope Model EC-600WL v2 (K160196)

Intended Use / Indications for Use:

EB-530US is intended for the observation, diagnosis, and endoscopic treatment of the trachea, bronchial tree and surrounding organs using ultrasonic images. It is used with a FUJIFILM ultrasonic processor, video processor, light source, other peripheral equipment and endoscopic accessories. It is not intended for use on children and infants.

Device Description:

FUJIFILM Ultrasonic Endoscope EB-530US is an ultrasonic bronchoscope that emits ultrasound waves and scans the reflected signals to provide ultrasonic images when used in combination with an ultrasonic processor.

Technological Characteristics:

The proposed devices EB-530US differ from the predicate devices in the following minor modifications:

- Compatibility with Video Processor VP-7000 and Light Source BL-7000 (K163675).
- Compatibility with Ultrasonic Processor SU-1 (K153206).
- Compliance to IEC60601-1 edition 3.1 and IEC60601-2-37 edition 2.1 to support compatibility with VP-7000, BL-7000, and SU-1.
- Expansion of transport and storage conditions to a temperature range of -20°C to 60°C and a humidity range of 10 to 85% RH.
- Use of a new epoxy resin in the manufacturing process. Both the new and original epoxy resins can be used for repair.

Performance Data:

Electrical safety of the proposed device was evaluated using the following standards: ANSI/AAMI ES 60601-1:2012, IEC 60601-1-2:2007, IEC 60601-1-6:2013, IEC 60601-2-18:2009, and IEC 60601-2-37:2015.

The proposed device EB-530US was adopted into biocompatibility testing conducted on reference device EC-600WL v2 using the following consensus standards:
ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

Storage and transportation testing was conducted on the proposed device EB-530US to validate the expanded storage and transportation conditions.

Fujifilm conducted the following performance testing on the proposed device EB-530US to ensure that the modified device performs equivalently to the predicate device:

- Field of view
- Bending capability
- Suction rate
- Working length
- Forceps channel diameter
- Viewing direction
- Resolution
- LG output
- Axial resolution
- Lateral resolution
- Penetration depth

In all cases, the device met the pre-defined acceptance criteria for the test.

Substantial Equivalence:

The company's EB-530US has the same intended use and indications for use as the previously cleared predicate EB-530US (K121035). In addition, the proposed device has similar technological characteristics and principles of operation as the predicate. The minor differences between the proposed device and their predicate device do not raise new or additional questions of safety or effectiveness of the proposed device. Thus, the proposed device EB-530US is substantially equivalent to the predicate device.

Conclusions:

The modified EB-530US is substantially equivalent to the predicate EB-530US and conforms to applicable medical device safety and performance standards.