July 27, 2018

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

Re: K181763
Trade/Device Name: FUJIFILM Ultrasonic Endoscopes EG-530UT2 and EG-530UR2
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDS, ITX
Dated: July 2, 2018
Received: July 3, 2018

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,

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181763

Device Name
FUJIFILM Ultrasonic Endoscopes EG-530UT2 and EG-530UR2

Indications for Use *(Describe)*
EG-530UT2 and EG-530UR2 are intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, diagnosis, and endoscopic treatment. The product is intended to be used with a Fujifilm ultrasonic processor. This product 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 Endoscopes EG-530UT2 and EG-530UR2

Date: July 2, 2018

Submitter's Information:

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

Contact Person:

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Specialist, Regulatory Affairs
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Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM Ultrasonic Endoscopes EG-530UT2 and EG-530UR2
Common Name:	Video Endoscope
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Classification:	Endoscope and accessories, 21 C.F.R. § 876.1500 Diagnostic ultrasonic transducer, 21 C.F.R. § 892.1570
Product Code:	FDS, ITX

Predicate Device:

Fujifilm Ultrasonic Endoscopes EG-530UT2 and EG-530UR2 (K120446)

Reference Device:

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

Intended Use / Indications for Use:

EG-530UT2 and EG-530UR2 are intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, diagnosis, and endoscopic treatment. The product is intended to be used with a Fujifilm ultrasonic processor. This product is not intended for use on children and infants.

Device Description:

FUJIFILM Ultrasonic Endoscopes EG-530UT2 and EG-530UR2 are upper gastrointestinal endoscopes that emit ultrasound waves and scan the reflected signals to provide ultrasonic images when used in combination with an ultrasonic processor.

Technological Characteristics:

The proposed devices EG-530UT2 and EG-530UR2 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.
- Other minor material changes

Performance Data:

Electrical safety of the proposed devices was evaluated using 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 devices EG-530UT2 and EG-530UR2 were 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 devices EG-530UT2 and EG-530UR2 to validate the expanded storage and transportation conditions.

Fujifilm conducted the following performance testing on the proposed devices EG-530UT2 and EG-530UR2 to ensure that the modified devices perform equivalently to the predicate devices:

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

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

Substantial Equivalence:

The company's EG-530UT2 and EG-530UR2 has the same intended use and indications for use as the previously cleared predicates EG-530UT2 and EG-530UR2 (K120446). In addition, the proposed devices have similar technological characteristics and principles of operation as their predicates. The minor differences between the proposed devices and their predicate devices do not raise new or additional questions of safety or effectiveness of the proposed devices. Thus, the proposed devices EG-530UT2 and EG-530UR2 are substantially equivalent to their predicate devices.

Conclusions:

The modified EG-530UT2 and EG-530UR2 are substantially equivalent to the predicate EG-530UT2 and EG-530UR2 and conform to applicable medical device safety and performance standards.