October 2, 2018

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

Re: K182051
Trade/Device Name: FUJIFILM Duodenoscope Model ED-530XT
Regulation Number: 21 CFR § 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDT
Dated: September 19, 2018
Received: September 20, 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/pmncfm 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,

[Signature]
Jeffrey W. Cooper -S
2018.10.02 21:34:02
-04'00'

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
Indications for Use

510(k) Number (if known)
K182051

Device Name
FUJIFILM Duodenscope Model ED-530XT

Indications for Use (Describe)
ED-530XT is intended for the visualization of the duodenum and upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
510(k) SUMMARY

FUJIFILM Duodenoscope Model ED-530XT

Date: July 30, 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
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Facsimile: (201) 995-2452
E-Mail: jeffrey.wan@fujifilm.com

Identification of the Proposed Device:

Proprietary/Trade Name: FUJIFILM Duodenoscope Model ED-530XT
Common Name: Endoscope
Device Class: Class II
Review Panel: Gastroenterology/Urology
Classification: Endoscope and accessories, 21 C.F.R. § 876.1500
Product Code: FDT

Predicate Device:

FUJIFILM Duodenoscope Model ED-530XT (K152257)

Intended Use / Indications for Use:

ED-530XT is intended for the visualization of the duodenum and upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

Device Description:

FUJIFILM Duodenoscope Model ED-530XT is 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 complementary Charge-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
The endoscope consists of electronic components needed to operate the endoscope when plugged into the video processor and the light source. The endoscope is used in combination with FUJIFILM’s video processors, light sources and peripheral devices such as monitor, printer, foot switch, and cart.

Technological Characteristics:

The proposed device ED-530XT differs from the predicate device in the following minor modifications:

- Compatibility with Video Processor VP-7000 and Light Source BL-7000 (K163675).
- Compliance to IEC60601-1 edition 3.1 to support compatibility with VP-7000 and BL-7000.
- 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.
- Compatibility with disposable cleaning brushes WB11003DV and WB7025DC.

Performance Data:


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

- Field of view
- Bending capability
- Air supply rate
- Water supply rate
- Suction rate
- Working length
- Forceps standing angle
- Forceps standing tension
- Forceps channel diameter
- Viewing direction
- Resolution
- LG output
In all cases, the devices met the pre-defined acceptance criteria for the test.

**Substantial Equivalence:**

The company's ED-530XT has the same intended use and indications for use as the previously cleared predicate ED-530XT (K152257). In addition, the proposed device has similar technological characteristics and principles of operation as the predicate. 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 device ED-530XT is substantially equivalent to its predicate device.

**Conclusions:**

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