September 27, 2019

FUJIFILM Corporation
% Kamila Sak
Specialist, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K191747
Trade/Device Name: FUJIFILM Duodenoscope Model ED-580XT
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDT
Dated: June 28, 2019
Received: July 1, 2019

Dear Kamila Sak:

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
Martha W. Betz, Ph.D.
Acting Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K191747

Device Name

FUJIFILM Duodenoscope Model ED-580XT

Indications for Use *(Describe)*

This device 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.

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510(k) SUMMARY

FUJIFILM Corporation's
FUJIFILM Duodenoscope Model ED-580XT

Date: September 26, 2019

Submitter's Information:

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

Contact Person:

Kamila Sak
Specialist, Regulatory Affairs
Telephone: (347) 577-2309
E-Mail: kamila.sak@fujifilm.com

Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM Duodenoscope Model ED-580XT
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-580XT (K181745)

Intended Use / Indications for Use

FUJIFILM Duodenoscope Model ED-580XT 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-580XT 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 consists of electronic components needed to operate the endoscope when plugged in to 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.

Comparison of Technological Characteristics

The proposed device ED-580XT differs from the predicate device in the following minor modifications:

- Material changes to distal end section
- Change to sterilization procedure
- Conformance to IEC 60601-1-2:2014

Performance Data

Electromagnetic compatibility of the subject device was evaluated using following standards: IEC 60601-1-2:2014.

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 performed in accordance with FDA's guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," published June 16, 2016.

Sterilization of the subject device were evaluated according to the following consensus standards: AAMI TIR12:2010, AAMI TIR30:2011. Validation of the 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 air supply
- Rate of water supply
- Rate of suction
- Working length
- Forceps standing angle
- Forceps standing tension

- Diameter of forceps channel
- Viewing direction
- Resolution
- LG output

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

Substantial Equivalence

The company's ED-580XT has the same intended use and indications for use as the previously cleared predicate ED-580XT (K181745). In addition, the proposed device has similar technological characteristics and principles of operation as the predicate. The minor differences between the proposed and predicate devices do not raise new or additional questions of safety or effectiveness of the proposed devices. Thus, the proposed device ED-580XT is substantially equivalent to the predicate device.

Conclusions

The modified ED-580XT is substantially equivalent to the predicate ED-580XT and conforms to applicable medical device safety and performance standards.