March 28, 2019

FUJIFILM Corporation
% Jeffrey Wan
Specialist, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
40 Boroline Road
Allendale, NJ 07401

Re: K181745
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: February 22, 2019
Received: February 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/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,

Mark J. Antonino -S

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K181745

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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 Corporation's**

**FUJIFILM Duodenoscope Model ED-580XT**

**Date:** March 28, 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 Device:**

Proprietary/Trade Name: FUJIFILM Duodenoscope Model ED-580XT
Common Name: Endoscope
Device Class: Class II
Review Panel: Gastroenterology/Urology

**Classification Information:**

Classification Name: Endoscope and accessories
CFR Section: 21 CFR 876.1500
Product Code: FDT

**Predicate Device:**

FUJIFILM Duodenoscope Model ED-530XT (K152257)

**Reference Devices:**

FUJIFILM Endoscope Model EC-760R-V/L (K172916)
EVIS EXERA II Duodenovideoscope Olympus TJF Type Q180V (K143153)

**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. All of these combinations were previously cleared in K152257 and K172916.

FUJIFILM Duodenoscope Model ED-580XT differs from the predicate device ED-530XT in terms of technological characteristics and materials. The reference devices EC-760R-V/L and TJF-Q180V support substantial equivalence with respect to some of these differences. Furthermore, the subject device and predicate device share the same mode of operation and intended use.

**Comparison of Technological Characteristics**

A summary of major differences between the subject device ED-580XT and the predicate device ED-530XT is provided as follows:

- Use of a single-use, removable distal end cap, DC-07D
- Use of the "G7" control portion, which has previously been cleared under K172916.
- Use of the "G-Lock" guidewire locking system. Similar technology has been previously cleared under K143153.
- Introduction of a new feature, "Advanced Force Transmission"
- Increase of maximum angle of endotherapy devices via the forceps elevator
- Compatibility with different video processors, light sources, and other accessories

**Performance Data**

Electrical safety of the subject device was evaluated using following standards: ANSI/AAMI ES60601-1:2012, 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.

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, ISO 11135:2014. 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.

Usability testing was conducted according to IEC 62366-1:2015 and the FDA guidance, "Applying Human Factors and Usability Engineering to Medical Devices," published February 3, 2016.

Bench testing was conducted on the subject device to validate the functionality of the G-Lock, Advanced Force Transmission, the modified forceps elevator, and the removable distal end cap.

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

**Substantial Equivalence**

The subject device FUJIFILM Duodenoscope Model ED-580XT is substantially equivalent to the predicate device, FUJIFILM Duodenoscope Model ED-530XT (K152257). The subject device has the same intended use, similar indications, similar technological characteristics and principles of operation as that of the predicate device. Technological changes to the predicate device ED-530XT have previously been cleared for the reference device EC-760R-V/L. Although material changes were made to the subject device, these materials were already present in the predicate device. Thus, the subject device ED-580XT is substantially equivalent to the predicate device.

**Conclusions**

The subject device FUJIFILM Duodenoscope Model ED-580XT is substantially equivalent to the predicate device 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 device is substantially equivalent in performance to the predicate device. Although material changes were made to the subject device, these materials were already present in the predicate device. Thus, the subject device FUJIFILM Duodenoscope Model ED-580XT is substantially equivalent to the predicate device, FUJIFILM Duodenoscope Model ED-530XT (K152257).