DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 21, 2017

FUJIFILM Medical Systems U.S.A., Inc.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, DC 20004

Re: K152257
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: May 30, 2017
Received: May 30, 2017

Dear John J. Smith:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

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 on last page

510(k) Number *(if known)*

K152257

Device Name

Fujifilm Duodenoscope Model ED-530XT

Indications for Use *(Describe)*

The Fujifilm Duodenoscope Model 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.

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510(k) SUMMARY

FUJIFILM Medical Systems U.S.A., Inc.'s
Fujifilm Duodenoscope Model ED-530XT

Submitter's Information

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Date Prepared: May 30, 2017

Identification of the Subject Device:

Proprietary/Trade Name:	Fujifilm Duodenoscope Model ED-530XT
Common Name:	Video Endoscope
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Classification Information:

Endoscope and Accessories (Flexible/Rigid), 21 C.F.R. § 876.1500
Product Code: FDT

Primary Predicate

Fujinon G5 Duodenoscope ED-450XT5 / ED-250XT5 (K042076)

Intended Use / Indications for Use

The Fujifilm Duodenoscope Model 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.

Technological Characteristics

The Fujifilm Duodenoscope Model ED-530XT is comprised of three main sections: an operation section, an insertion portion, and an umbilicus. The operation section controls the angulation (up/down/left/right) of the distal end of the endoscope. The insertion portion contains glass fiber bundles, several channels and a CCD image sensor. 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 sensor to capture an image and display it on the monitor. The endoscope also contains several channels to deliver air/water and provide suction, as well as a forceps channel. The forceps channel is used to introduce endoscope accessories such as biopsy forceps during the procedure. The umbilicus section consists of electronic components needed to operate the endoscope when plugged in to the video processor and the light source.

The subject device is used in combination with Fujifilm's EPX-4400 (K944620), EPX-4400HD (K944620), and EPX-4440HD (K102466, K140149) video processors and light sources, as well as peripheral devices such as water tank, endoscope accessories, monitor, printer, electrosurgical instruments, foot switch, and cart. All of the peripheral accessories are substantially similar to those cleared in the predicate submission, with the exception of a new single use Elevator Cleaning Brush WB1318DE.

The differences between the subject and predicate device are as follows:

- Distal end design differences (e.g., changes in materials and dimensions);
- Reduction in the diameter of the flexible portion and insertion portion;
- Optical differences (e.g., modified viewing direction and CCD sensor); and
- Modifications to the device's labeled reprocessing procedure.

Performance Data

EMC and electrical safety of the subject devices were evaluated using the following consensus standards: IEC 60601-1-2:2007; ANSI/AAMI ES60601-1:2005; and IEC 60601-2-18:2009.

Biocompatibility of the subject device was evaluated in accordance with ISO 10993.

Cleaning, disinfection, and sterilization were evaluated according to the following consensus standards: AAMI TIR12:2010, AAMI TIR30:2011. 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.

Endoscope specific testing was conducted using the consensus standard ISO8600-1:2013.

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
- Resolution
- Light Guide (LG) Output

Performance testing and design analysis was conducted to demonstrate the safety and effectiveness of the elevator wire channel seal, as well as distal end cap seal strength and integrity.

Substantial Equivalence

The ED-530XT is substantially equivalent the ED-450XT5. The ED-530XT has the same intended use, indications, and principles of operation, and similar technological characteristics, as its predicate device. The minor technological differences between the ED-530XT and its predicate devices were made for the purpose of overall product enhancement and general technological advancement, and do not raise different questions of safety or effectiveness. Performance data demonstrate that the ED-530XT is substantially equivalent to the ED-450XT5. Thus, the ED-530XT is substantially equivalent to the predicate device.

Conclusions

Based on device description, comparison to predicate device, and performance bench data described above, Fujifilm believes that the ED-530XT is substantially equivalent to the predicate device ED-450XT5 based on intended use/indications for use and technological characteristics. The minor technological differences between the subject endoscope and its predicate device raise no new issues of safety or effectiveness. Bench testing data demonstrated that the subject endoscope is as safe and effective, and performs as well or better, than the predicate device. Thus, the device is substantially equivalent to the predicate device.