July 16, 2019

FUJIFILM Corporation
% Jeffrey Wan
Specialist, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
419 West Ave
Stamford, CT 06902

Re: K183572
Trade/Device Name: FUJIFILM Endoscope Models EG-760CT, EC-760P-V/L and EC-740T/L
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FDF, FDS
Dated: June 20, 2019
Received: June 21, 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/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
Shanil Haugen, 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)*
K183572

Device Name
FUJIFILM Endoscope Models EG-760CT, EC-760P-V/L and EC-740T/L

Indications for Use *(Describe)*
FUJIFILM Endoscope Model EG-760CT is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

FUJIFILM Endoscope Models EC-760P-V/L and EC-740T/L are intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 Endoscope Models EG-760CT, EC-760P-V/L, and EC-740T/L

Date: July 15, 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
Senior Regulatory Affairs Specialist
Telephone: (201) 675-8947
E-Mail: jeffrey.wan@fujifilm.com

Identification of the Proposed Devices:

Proprietary/Trade Name:	FUJIFILM Endoscope Models EG-760CT, EC-760P-V/L and EC-740T/L
Common Name:	Endoscope
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Classification Information:

Classification Name	CFR Section	Product Codes
Endoscope and accessories	21 CFR 876.1500	FDS, FDF

Predicate Devices:

- FUJIFILM Endoscope Models EG-760R and EC-760R-V/L (K172916)

Intended Use / Indications for Use

FUJIFILM Endoscope Model EG-760CT is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

FUJIFILM Endoscope Models EC-760P-V/L and EC-740T/L are intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

Device Description

FUJIFILM Endoscope Models EG-760CT, EC-760P-V/L and EC-740T/L are 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 either a complementary metal-oxide-semiconductor (CMOS, in 760 series models) or charged-coupled device (CCD, in EC-740T/L) 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 CMOS or 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 into the video processor and the light source. The endoscopes are 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 K172916.

Comparison of Technological Characteristics

FUJIFILM Endoscope Models EG-760CT, EC-760P-V/L and EC-740T/L differ from the predicate devices EG-760R and EC-760R-V/L in terms of technological characteristics and materials. The subject and predicate devices share the same mode of operation and intended use.

A summary of differences between the subject devices EG-760CT, EC-760P-V/L and EC-740T/L and the predicate devices EG-760R and EC-760R-V/L is provided as follows:

- Introduction of new features, "Advanced Force Transmission" and "Adaptive Bending" for EC-760P-V/L and EC-740T/L
- Dimensional changes to the insertion portion and instrument channel
- Material changes to the insertion portion, instrument channel, and water jet channel

Performance Data

Electrical safety of the subject device was evaluated using following standards: ANSI/AAMI ES 60601-1:2012, 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. Biocompatibility testing was conducted in accordance with the FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process",* issued June 16, 2016.

Endoscope specific testing was conducted using the following consensus standards: ISO 8600-1:2015, ISO 8600-3:1997, and ISO 8600-4:2014.

Software specific testing was conducted using the following consensus standard: ANSI/AAMI/IEC 62304:2006. The software validation activities were performed in accordance with the FDA Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued on May 11, 2005.

Cleaning, high-level disinfection, and sterilization of the subject device 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.

Bench testing was conducted on EC-760P-V/L and EC-740T/L to validate the Advanced Force Transmission and Adaptive Bending features. Comparative bench testing was conducted on the subject device EG-760CT and the predicate device EG-760R to evaluate the rate of suction.

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

Substantial Equivalence

The subject devices FUJIFILM Endoscope Models EG-760CT, EC-760P-V/L and EC-740T/L are substantially equivalent to the predicate devices, FUJIFILM Endoscope Models EG-760R and EC-760R-V/L (K172916). The subject devices have the same intended use/indications for use and substantially similar technological characteristics and principles of operation as that of the predicate devices. Material changes to the predicate devices have been validated through biocompatibility testing. Thus, the subject devices FUJIFILM Endoscope Models EG-760CT, EC-760P-V/L and EC-740T/L are substantially equivalent to the predicate devices.

Conclusions

The subject devices FUJIFILM Endoscope Models EG-760CT, EC-760P-V/L and EC-740T/L are substantially equivalent to the predicate devices 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 devices are substantially equivalent in performance to the predicate devices. The difference in materials between subject and predicate devices has been validated through biocompatibility testing. Thus, the subject devices FUJIFILM Endoscope Models EG-760CT, EC-760P-V/L and EC-740T/L are substantially equivalent to the predicate devices, FUJIFILM Endoscope Models EG-760R and EC-760R-V/L (K172916).