



May 7, 2019

FUJIFILM Corporation
% Liza Dejesa-Jamanila
Director, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K190649
Trade/Device Name: FUJIFILM Endoscope Model EC-760S-V/L
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: March 12, 2019
Received: March 13, 2019

Dear Liza Dejesa-Jamanila:

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,


Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Acting Assistant Division Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of Gastorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K190649

Device Name

FUJIFILM Endoscope Model EC-760S-V/L

Indications for Use (Describe)

EC-760S-V/L is 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.

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510(k) SUMMARY

FUJIFILM Endoscope Model EC-760S-V/L

Date: March 12, 2019

Submitter's Information:

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

Contact Person:

Liza Dejesa-Jamanila
Director, Regulatory Affairs
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Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM Endoscope Model EC-760S-V/L
Common Name:	Colonoscope
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Classification:	Endoscope and accessories, 21 C.F.R. § 876.1500
Product Code:	FDF

Predicate Device:

FUJIFILM Endoscope Model EC-760R-V/L (K172916)

Intended Use / Indications for Use:

EC-760S-V/L is 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 Model EC-760S-V/L 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 metal-oxide-semiconductor (CMOS) 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 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.

Technological Characteristics:

The proposed device EC-760S-V/L differs from the predicate device in the following minor modifications:

- Dimensional and material changes to the insertion portion
- Introduction of the "Advanced Force Transmission" and "Adaptive Bending" features

Performance Data:

Electrical safety of the proposed device was evaluated using the following standards: ANSI/AAMI ES 60601-1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2013, and IEC 60601-2-18:2009.

Biocompatibility of the proposed device was evaluated using the following consensus standards: ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

The proposed device EC-760S-V/L was adopted into the reprocessing validation of the predicate device EC-760R-V/L using 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.

The proposed device EC-760S-V/L was adopted into the photobiological safety testing of the predicate device EC-760R-V/L in accordance with IEC 62471:2006.

Bench testing was conducted on the subject device to validate the Advanced Force Transmission, Adaptive Bending features.

Fujifilm conducted the following performance testing on the proposed device EC-760S-V/L to ensure that the modified device performs equivalently to the predicate device:

- Field of view
- Bending capability
- Rate of air supply
- Rate of water supply
- Suction rate
- Working length

- Forceps channel diameter
- Viewing direction
- Resolution
- LG output

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

Substantial Equivalence:

The company's EC-760S-V/L has the same intended use and indications for use as the previously cleared predicate EC-760R-V/L (K172916). 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 EC-760S-V/L is substantially equivalent to the predicate device.

Conclusions:

The modified EC-760S-V/L is substantially equivalent to the predicate EC-760R-V/L and conforms to applicable medical device safety and performance standards.