March 1, 2018

Fujifilm Corporation
Shraddha More
Specialist, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc
10 High Point Drive
Wayne, New Jersey 07470

Re: K172916
Trade/Device Name: FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L, and EC-760ZP-V/L, and FUJIFILM Water Tank Model WT-603
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS, FDF
Dated: January 26, 2018
Received: January 29, 2018

Dear Shraddha More:

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.

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.

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,

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)*

K172916

Device Name

FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L and EC-760ZP-V/L and FUJIFILM Water Tank Model WT-603

Indications for Use *(Describe)*

FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L, and EC-760ZP-V/L have following indications for use.

FUJIFILM Endoscope Models EG-760R and EG-760Z are upper gastrointestinal endoscopes 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-760R-V/L and EC-760ZP-V/L are lower gastrointestinal endoscopes intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine. .

FUJIFILM Water Tank Model WT-603 has following indications for use.

The Water Tank Model WT-603 is intended for use in combination with FUJIFILM 700 system scopes to deliver air and water through the endoscope under the management of a physician in medical facilities. Do not use this product for any other purpose.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

FUJIFILM Medical Systems U.S.A., Inc.'s
FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L and EC-760ZP-V/L

Date: March 1, 2018

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.,
Endoscopy Division
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Person

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Identification of the Proposed Device

Proprietary/Trade Name:	FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L, EC-760ZP-V/L and Water Tank Model WT-603
Common Name:	Endoscopes
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Classification Information

Classification Name	CFR Section	Product Codes
Gastroscope And Accessories, Flexible/Rigid	21 CFR 876.1500	FDS
Colonoscope And Accessories, Flexible/Rigid	21 CFR 876.1500	FDF

Predicate Devices

- Fujifilm 600 Series Endoscope Model EG-600WR and Water Tank Model WT-4 (K132210)
- Fujifilm Video Colonoscope Model EC-600WL v2 (K160196)

Intended Use / Indications for Use

FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L, and EC-760ZP-V/L have following indications for use.

FUJIFILM Endoscope Models EG-760R and EG-760Z are 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-760R-V/L and EC-760ZP-V/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.

FUJIFILM Water Tank Model WT-603 has following indications for use.

This product is intended for use in combination with FUJIFILM 700 system scopes to deliver air and water through the endoscope under the management of a physician in medical facilities. Do not use this product for any other purpose.

Device Description

FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L and EC-760ZP-V/L are comprised of three general sections: a control portion, an insertion portion and an umbilicus. The control portion controls the angulation of the endoscopes. This portion also controls the flexibility of the distal end in the endoscopes. 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.

FUJIFILM Water Tank Model WT-603 consists of a container which holds the sterile water and a tank cover which provides delivery of water through the channel tube to the distal end of an Endoscope.

The subject devices 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 K132210, K162622 and K163675.

The main differences between the subject and predicate devices are provided below.

Comparison of Technological Characteristics

For FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L and EC-760ZP-V/L, main differences from predicate device endoscopes are as follows:

- Introduction of optical zoom function for EG-760Z and EC-760ZP-V/L
- Introduction of flexibility adjustment mechanism for EC-760R-V/L and EC-760ZP-V/L
- Introduction of Scope Connector with contactless connecting technology and software and CPU installation for in the subject endoscopes to accommodate this functionality.
- Minor material changes in insertion portion, instrument channel, Air/Water channel, and water jet channel due to supplier availability.

For FUJIFILM Water Tank Model WT-603, main differences from the predicate Water Tank WT-4 are materials and compatible endoscope models.

Performance Data

FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L and EC-760ZP-V/L have been subjected to the bench performance testing as below. The devices met pre-determined acceptance criteria in compliance with the relevant standards

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 devices 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.

The endoscopes met performance specifications in the following additional testing:

- Field of view
- Bending capability
- Rate of suction
- Working length
- Diameter of forceps channel
- Viewing direction
- LG output
- Flexibility adjustment mechanism

FUJIFILM Water Tank Model WT-603 has been subjected to the bench performance testing as below. The device met pre-determined acceptance criteria in compliance with the relevant standards

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

Cleaning, disinfection, and sterilization of subject devices 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.

The endoscope valve AW-603 which controls the supply of Air/Water from Water Tank to the endoscope, has been validated for its efficiency in preventing the backflow of the fluids from the endoscope to the Water Tank. The valve met pre-determined acceptance criteria in compliance with the FDA's Guidance "Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes, published on January 20, 2015".

Substantial Equivalence

FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L, EC-760ZP-V/L and Water Tank WT-603 have the same intended use, indications for use and substantially technological characteristics, and principles of operation as their respective predicate devices. The key differences between the predicate and subject endoscope models are new functionalities, known as optical zoom function and flexibility adjustment mechanism, which are not present in their respective predicate devices, but have been supported by substantially similar zoom magnification function in Olympus EVIS EXERA Gastrointestinal Videoscopes GIF-Q160Z (K011151) and flexibility adjustment function in Olympus EVIS EXERA III Gastrointestinal Videoscopes PCF-H190L (K112680), which are cited as reference devices. Additionally, the subject devices are installed with Scope Connector, which utilizes wireless contact, electromagnetic induction for power supply and optical communication. The same integrated connector technology has been submitted as "contactless connecting technology" under pre-sub Q151022 in "Section I: Device Description, Subsection A: Technological Characteristics" and subsequently cleared under premarket notification K163675 for Processor VP-7000 and Light Source BL-7000, which are used in combination with the subject endoscope models. More information is provided in substantial equivalence section.

The main differences between the predicate and subject Water Tank Model are compatibility with different endoscope models and materials.

Bench testing data demonstrated that the subject endoscope models have substantially equivalent performance and safety to their respective predicate devices. The materials of the Water Tank have been changed due to supplier availability.

In summary, these minor differences between FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L, EC-760ZP-V/L and Water Tank WT-603 and their respective predicate devices were made for the purpose of overall product enhancement and general technological advancement, and raise no new issues of safety or effectiveness. The material changes in the subject device do not raise new concerns regarding biocompatibility as discussed in section XVII. Performance data demonstrated that FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L, EC-760ZP-V/L and Water Tank WT-603 have substantially equivalent performance to their respective predicate

devices. The subject devices are successfully validated for the electrical safety and reprocessing instructions, supporting their safety equivalent to the predicate devices.

Conclusions

The subject devices FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L, EC-760ZP-V/L and Water Tank WT-603 are substantially equivalent to their respective predicate devices based on the same intended use, substantially similar indications for use and technological characteristics. The differences in the indications for use and technological characteristics and materials between the subject devices and their respective predicate devices raise no new issues of safety or effectiveness. Bench testing data demonstrated that the subject devices have substantially equivalent performance to their respective predicates. Additional performance testing has demonstrated that new functions included in the subject devices do not raise concerns regarding safety and efficacy of the subject devices. Thus, the subject devices FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L, EC-760ZP-V/L and Water Tank WT-603 are substantially equivalent to their respective predicate devices, Fujifilm 600 Series Endoscope Model EG-600WR and Water Tank WT-4 (K132210) and Fujifilm Video Colonoscope EC-600WL v2 (K160196).