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JAN 10 2014

510(k) Summary

Date: January 9, 2014

Submitter's Information:

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

Contact Persons:

Gina Walljasper
Director, Quality and Regulatory Compliance
Telephone: (973) 686-2636
Facsimile: (973) 686-2616
E-Mail: gwalljasper@fujifilm.com

Identification of the Proposed Devices:

Proprietary/Trade Name:	Fujifilm 600 Series Endoscopes EC-600WL and EG-600WR Water Tank WT-4
Common Name:	Video Endoscope
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Classification Information:	

Classification Name	CFR Section	Product Codes
Colonoscope and Accessories (Flexible/Rigid)	21 CFR 876.1500	FDF
Gastroscope and Accessories (Flexible/Rigid)	21 CFR 876.1500	FDS

I. INDICATIONS FOR USE

Fujifilm 600 Series Endoscope EC-600WL: This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

Fujifilm 600 Series Endoscope EG-600WR: The device is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

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Fujifilm 600 Series (Water Tank, WT-4): The device is intended for use in combination with Fujinon/Fujifilm Endoscopes 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.

II. DEVICE DESCRIPTION

Fujifilm 600 Series Endoscopes, EC-600WL and EG-600WR, are modified versions of the legally marketed Fujinon Colonoscopes EC-530HL2 and EC-530LS2 in K112391, and Fujinon G5 Gastroscope EG-450WR5 in K042043 respectively. Just like K112391, the proposed EC-600WL is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine. The proposed EG-600WR is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum, this is similar to K042043.

The endoscopes are comprised of three general 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 complementary metal–oxide–semiconductor (CMOS) 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 CMOS image sensor to capture an image and display it on the monitor. The endoscope also contains several channels to deliver air/water, provide suction, and 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 to the video processor and light source.

The proposed models are used in combination with Fujifilm's video processor, light source and peripheral devices (water tank, endoscopic accessories, monitor, printer, DVD recorder, electrosurgical instruments, foot switch, cart).

The intended use, scientific fundamental technology and operating principle of the Water Tank WT-4 accessory, remains the same as the legally marketed Water Tank WT-2.

The minor modifications to the proposed devices were made for the purpose of overall product enhancement and general technological advancement.

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III. SUMMARY OF STUDIES

The proposed devices have been subjected to and passed electrical safety and EMC test requirements.

Fujifilm 600 Series Endoscopes, EC-600WL and EG-600WR, and Water Tank WT-4 were evaluated in accordance with the following safety and performance requirements in addition to the applicable quality regulations:

ANSI/AAMI ES60601-1***	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC60601-1-2***	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Compatibility - Requirements and tests
IEC60601-2-18***	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment
ISO10993-1*	Biological evaluation of medical devices
ISO10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO8600-1**	Optics and photonics - Medical endoscopes and endotherapy devices
ISO8600-3	Optics and Optical instruments – Medical endoscopes and endoscopic accessories – Part 3: Determination of field of view and direction of view of endoscopes with optics
ISO8600-4	Optics and Optical instruments – Medical endoscopes and certain accessories – Part 4: Determination of maximum width of insertion portion

*Evaluation to ISO 10993-1 (Tested per ISO10993-5 and ISO-10993-10) was conducted for patient contact materials for 600 Series Endoscopes (direct and indirect) and Water Tank WT-4 (indirect only).

**Evaluation to ISO 8600-1 (Tested per ISO 8600-3 and ISO 8600-4) was conducted for 600 Series Endoscopes.

***Evaluation to ANSI/AAMI ES60601-1, IEC60601-1-2 and IEC60601-2-18 were conducted for 600 Series Endoscopes.

The reprocessing instructions were updated and validated. No clinical testing was conducted.

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IV. SUBSTANTIAL EQUIVALENCE

Fujifilm 600 Series Endoscopes, EC-600WL and EG-600WR, and Water Tank WT-4 are substantially equivalent to the following devices:

Proposed Device	Legally Marketed Device(s)	510(k) #
Fujifilm 600 Series Endoscope EC-600WL	Fujinon Colonoscopes, EC-530HL2 and EC-530LS2	K112391
Fujifilm 600 Series Endoscope EG-600WR	Fujinon G5 Gastroscope EG-450WR5	K042043
Water Tank WT-4	Water Tank WT-2	K944620

V. CONCLUSION

Fujifilm 600 Series Endoscopes, EC-600WL and EG-600WR, and Water Tank WT-4 are substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2014

FUJIFILM Medical Systems U.S.A., Inc.
Gina Walljasper
Director, Quality and Regulatory Compliance
10 High Point Drive
Wayne, NJ 07470

Re: K132210
Trade/Device Name: Fujifilm 600 Series Endoscopes EC-600WL and EG-600WR
Fujifilm 600 Series (Water Tank, WT-4)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF, FDS
Dated: December 20, 2013
Received: December 23, 2013

Dear Gina Walljasper,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner -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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132210

Device Name
Fujifilm 600 Series (Water Tank, WT-4)

Indications for Use *(Describe)*

This product is intended for use in combination with Fujinon/Fujifilm Endoscopes 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)*

Herbert P. Lerner -S
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510(k) Number (if known): K132210

Device Name: Fujifilm 600 Series Endoscopes EC-600WL and EG-600WR

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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