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

October 18, 2016

Fujifilm Medical Systems USA, Inc.
Shraddha More
Specialist, Regulatory Affairs and Quality Assurance
10 High Point Drive
Wayne, New Jersey 07470

Re: K162622
Trade/Device Name: Fujifilm Endoscope Models EC-600HL and EC-600LS
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FDF
Dated: September 19, 2016
Received: September 20, 2016

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.

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,

For Division

Douglas Silverstein -S
2016.10.18 13:53:51 -04'00'

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 below.

510(k) Number *(if known)*
K162622

Device Name
Fujifilm Endoscope Models EC-600HL and EC-600LS

Indications for Use *(Describe)*
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.

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's EC-600HL and EC-600LS

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:

Shraddha More
Specialist, Regulatory Affairs and Quality Assurance
Telephone: (973) 686-2627 Ext. 522627
Facsimile: (973) 633-8818
E-Mail: smore@fujifilm.com

Date Prepared: January 27, 2017

Identification of the Subject Device:

Proprietary/Trade Name:	Fujifilm Endoscope Models EC-600HL and EC-600LS
Common Name:	Video Endoscope
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Classification Information:

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

Primary Predicate

Fujifilm Endoscope Models EC-600HL and EC-600LS (K143732)

Purpose of the Special 510(k) notice

The EC-600HL and EC-600LS are modifications of predicate EC-600HL and EC-600LS respectively

Intended Use

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.

Device Description

The modified Fujifilm Endoscope Models EC-600HL and EC-600LS are comprised of three main sections: an operation section, an insertion portion, and an umbilicus. The Table 5-1 describes the insertion and non-insertion portions of the devices. 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 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 **Figure 10-1** below shows main components of the endoscopes.

The subject device is used in combination with FUJIFILM's video processor, light source and peripheral devices such as water tank, endoscope accessories, monitor, printer, electrosurgical instruments, foot switch, and cart. All of these were previously cleared in K143732.

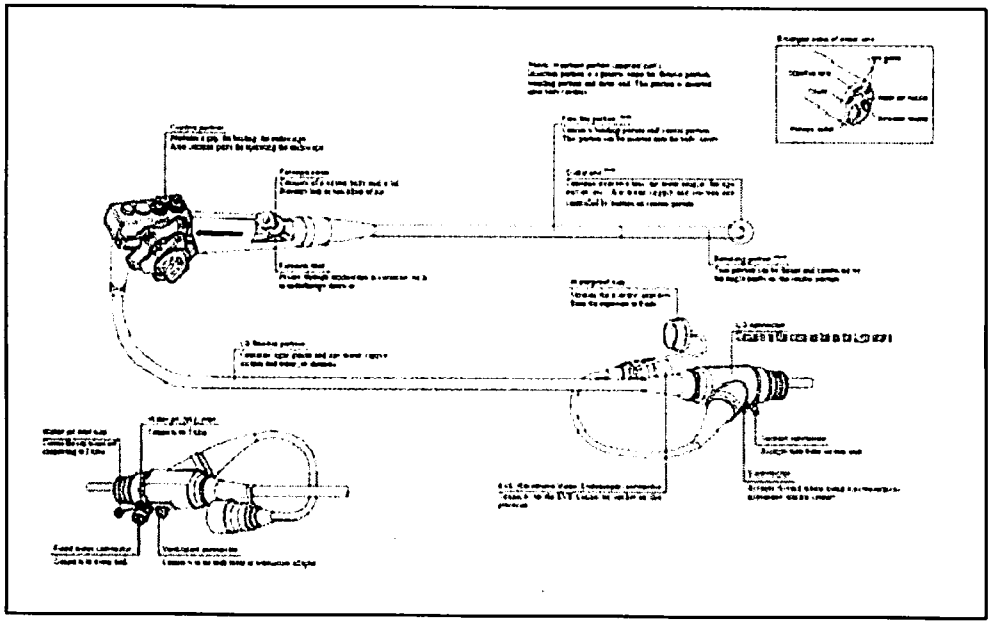


Figure 10-1: Components of the Endoscope EC-600HL and EC-600LS

Technological Characteristics

Table 10-1: Comparison between technological characteristics of EC-600HL and its predicate

		Predicate Device Model EC-600HL	**Proposed Device Model EC-600HL**
Device Name		Fujifilm Video Endoscope EC-600HL	Fujifilm Video Endoscope EC-600HL
510(k) Number		K143732	Pending
Indications for Use (IFU)		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.	Same as K143732
Viewing direction		Forward/ 0 degree	Same as K143732
Observation range		2-100mm	Same as K143732
Field of View		170 degrees	Same as K143732
Distortion characteristics		Orthogonal Projection	Same as K143732
Image sensors		CMOS	Same as K143732
Distal end diameter		12.8mm	Same as K143732
Flexible portion diameter		12.8mm	Same as K143732
Maximum insertion diameter		14.3mm	Same as K143732
Bending capability	Up	180 degrees	Same as K143732
	Down	180 degrees	Same as K143732
	Left	160 degrees	Same as K143732
	Right	160 degrees	Same as K143732
Forceps channel diameter		4.2mm	Same as K143732
Working length		1690mm	Same as K143732
Total length		1990mm	Same as K143732
WJ Function		c	Same as K143732
Location of WJ inlet		On the light guide connector	Same as K143732
Video Processor		EPX-4440HD - Light Source:XL-4450 - Processor:VP-4440HD	Same as K143732
Peripherals		Water Tank WT-2 Water Tank, WT-4	Same as K143732
		Endoscopic Accessory(i.e. Forceps)	Same as K143732
		Monitor	Same as K143732
		Printer	Same as K143732
		None	Same as K143732
		Electrosurgical Instruments	Same as K143732
		Foot Switch	Same as K143732
		Cart	Same as K143732

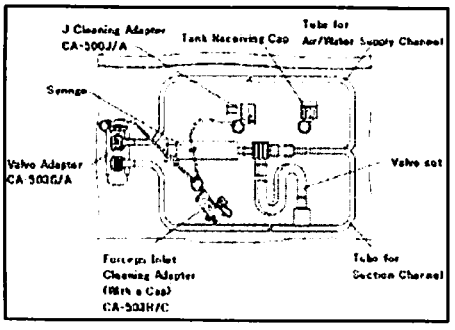
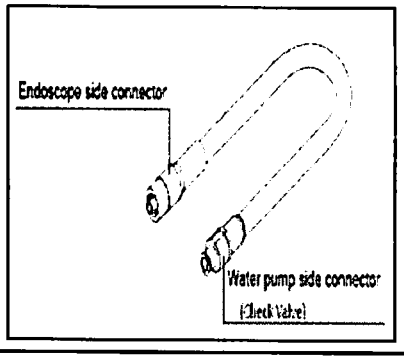
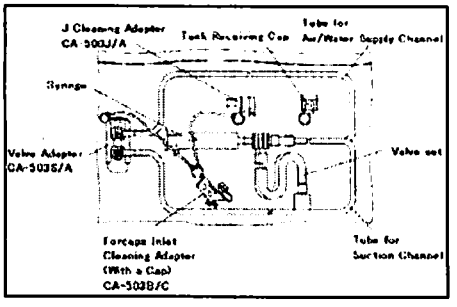
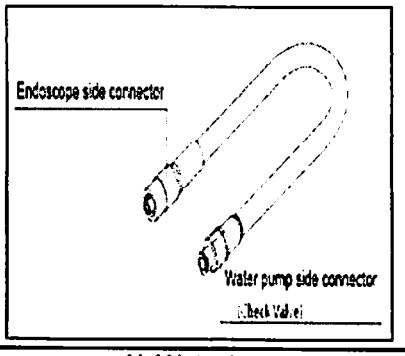
	Predicate Device Model EC-600HL	Proposed Device Model EC-600HL
Accessories	Cleaning Brush WB11002FW2	Same as K143732
	Channel Cleaning Brush WB5021FW2	Same as K143732
	Forceps Valve (FOV-DV7)	Same as K143732
	Ventilation Adapter (AD-7)	Same as K143732
	Cleaning Adapter Kit (CA-510/A)  	Same as K143732
	J Tube (JT-500)  	Same as K143732
	Air/Water button (AW-500)	Minor material and design modifications
	Suction button (SB-500)	Minor material and design modifications
	Water Jet Inlet cap	Same as K143732
Optional items	Air leak tester LT-7F	Same as K143732

Table 10-2: Comparison between technological characteristics of EC-600LS and its predicate

		Predicate Device Model EC-600LS	Proposed Device Model EC-600LS
Device Name		Fujifilm Video Endoscope	Fujifilm Video Endoscope
		EC-600LS	EC-600LS
510(k) Number		K143732	Pending
Indications for Use (IFU)		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.	Same as K143732
Viewing direction		Forward/ 0 degree	Same as K143732
Observation range		2-100mm	Same as K143732
Field of View		170 degrees	Same as K143732
Distortion characteristics		Orthogonal Projection	Same as K143732
Image sensors		CMOS	Same as K143732
Distal end diameter		11.5mm	Same as K143732
Flexible portion diameter		11.5mm	Same as K143732
Maximum insertion diameter		13.1mm	Same as K143732
Bending capability	Up	180 degrees	Same as K143732
	Down	180 degrees	Same as K143732
	Left	160 degrees	Same as K143732
	Right	160 degrees	Same as K143732
Forceps channel diameter		3.8mm	Same as K143732
Working length		1690mm	Same as K143732
Total length		1990mm	Same as K143732
WJ Function		Yes	Same as K143732
Location of WJ inlet		On the light guide connector	Same as K143732
Video Processor		EPX-4440HD Light Source:XL-4450 Processor:VP-4440HD	Same as K143732
Peripherals		Water Tank WT-2 Water Tank, WT-4	Same as K143732
		Endoscopic Accessory(i.e. Forceps)	Same as K143732
		Monitor	Same as K143732
		Printer	Same as K143732
		None	Same as K143732
		Electrosurgical Instruments	Same as K143732
		Foot Switch	Same as K143732
		Cart	Same as K143732

	Predicate Device Model EC-600HL	Proposed Device Model EC-600HL
Accessories	Cleaning brush WB11002FW2	Same as K143732
	Cleaning brush WB11002FW2	Same as K143732
	Channel Cleaning Brush WB5021FW2	Same as K143732
	Cleaning Adapter Kit (CA-510/A) 	Same as K143732
	Forceps Valve (FOV-DV7)	Same as K143732
	Ventilation Adapter (AD-7)	Same as K143732
	J Tube (JT-500) 	Same as K143732
	Air/Water button (AW-500)	Minor material and design modifications
	Suction button (SB-500)	Minor material and design modifications
	Water Jet Inlet cap	Same as K143732
Optional items	Air leak tester LT-7F	Same as K143732

Principles of Operation

The principles of operation of the FUJIFILM Endoscope Models EC-600HL and EC-600LS are identical to those of the predicate device, FUJIFILM 600 Series Endoscope EC-600HL and EC-600LS (K132210). All three devices utilize a retrograde approach for visualization of the areas of the lower digestive tracts.

Summary of the Design Modifications

The proposed devices have been modified from their corresponding predicate devices in their materials. A new epoxy resin will be used in modified devices instead of the current epoxy resin during their manufacturing. Both epoxy resins will be used for the repair of predicate as well as subject devices.

This material change does not affect the intended use or fundamental scientific technology of the proposed endoscopes; therefore the intended use and fundamental scientific technology of the proposed endoscopes remain the same as the legally marketed EC-600HL and EC-600LS (K143732). See **Table 10-1** and **Table 10-2** for a detailed similarities and differences comparison between the technological characteristics of proposed device and the legally marketed device.

Performance Data

Fujifilm conducted the following performance testing of the modified EC-600HL and EC-600LS to ensure that the modified device performs equivalently to the predicate EC-600HL and EC-600LS:

- Field of view
- Bending capability
- Rate of air supply
- Rate of water supply
- Rate of suction
- Working length
- Diameter of forceps channel
- Viewing direction
- Maximum insertion portion width
- Resolution
- LG output

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

Substantial Equivalence

EC-600HL and EC-600LS has the same intended use and similar indications, principles of operation, and technological characteristics as their predicate devices EC-600HL and EC-600LS. The minor differences in the modified devices technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the EC-600HL and EC-600LS are as safe and effective as their predicate devices EC-600HL and EC-600LS respectively. Thus, the modified EC-600HL and EC-600LS are substantially equivalent to their respective predicate devices.