March 15, 2018

FUJIFILM Corporation
% Jeffrey Wan
Specialist, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
10 High Point Drive
Wayne, NJ 07470

Re: K180405
Trade/Device Name: FUJIFILM Endoscope Models EC-600HL and EC-600LS
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: February 5, 2018
Received: February 14, 2018

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. 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,

Charles Viviano -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

VI. INDICATIONS FOR USE STATEMENT

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)*
K180405

Device Name

FUJIFILM Endoscope Models EC-600HL and EC-600LS

Indications for Use *(Describe)*

These devices 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)

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.

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:

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"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."

VII. 510(K) SUMMARY

510(k) SUMMARY

FUJIFILM Endoscope Models EC-600HL and EC-600LS

Submitter's Information:

FUJIFILM Corporation
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FDA Establishment Registration Number: 3001722928

Contact Person:

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Date Prepared: February 5, 2018

Identification of the Proposed 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:	Endoscope and accessories, 21 C.F.R. § 876.1500
Product Code:	FDF

Predicate Device:

Fujifilm Endoscope Models EC-600HL and EC-600LS, Fujifilm Medical Systems U.S.A, K162622

Intended Use / Indications for Use:

These devices 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 EC-600HL and EC-600LS are lower gastrointestinal endoscopes that capture images when used in combination with a video processor and light source. Light travels from the light source, through the glass fiber bundles in the endoscopes, and out 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.

Technological Characteristics:

A comparison of the technological characteristics between the modified and predicate devices is provided in the table below.

Table 7.1 – Comparison Chart for EC-600HL

	Proposed Device	Predicate Device
Device name	EC-600HL	EC-600HL
Common name	Endoscope and accessories	Endoscope and accessories
Manufacturer	FUJIFILM Corporation	FUJIFILM Corporation
510(k) number	To be assigned	K162622
Intended Use/Indications for Use	Same as K162622	The 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.
Appearance	Same as K162622	
Viewing direction	Same as K162622	Forward / 0 degrees
Observation range	Same as K162622	2-100mm
Field of view	Same as K162622	170 degrees
F# of the objective lens	Same as K162622	7
Resolution	Same as K162622	At 5mm of working distance: 0.056mm of line pair on the square wave chart is readable. At 100mm of working distance: 1.25mm of line pair on the square wave chart is readable.
Distortion characteristics	Same as K162622	Orthogonal Projection
Magnification of lens(es)	Same as K162622	0.3-0.01
Focal length	Same as K162622	0.9mm
Image sensors	Same as K162622	CMOS
# of Light Guide Fiber Bundles	Same as K162622	2800

		Proposed Device	Predicate Device
Distal end diameter		Same as K162622	12.8mm
Flexible portion diameter		Same as K162622	12.8mm
Maximum insertion diameter		Same as K162622	14.3mm
Bending capability	**Up**	Same as K162622	180 degrees
	Down	Same as K162622	180 degrees
	Left	Same as K162622	160 degrees
	Right	Same as K162622	160 degrees
Forceps channel diameter		Same as K162622	4.2mm
Working length		Same as K162622	1690mm
Total length		Same as K162622	1990mm
WJ Function		Same as K162622	available
Location of WJ inlet		Same as K162622	On the light guide connector
Video Processor		**Light source: BL-7000** **Processor: VP-7000** EPX-4440HD Light source: XL-4450 Processor: VP-4440HD **EPX-4440FN** **Light source: XL-4450FN** **Processor: VP-4440FN**	EPX-4440HD Light source: XL-4450 Processor: VP-4440HD
Video/Light guide connector		Same as K162622	500 Series
Peripherals		Same as K162622	Water Tank WT-2 Water Tank WT-4 Endoscopic Accessory (i.e. Forceps) Monitor Printer Electrosurgical Instruments Foot Switch Cart
Accessories		Same as K162622	Cleaning Brush (WB11002FW2) Cleaning Brush (WB5021FW2) Cleaning Adapter Kit (CA-510/A) Forceps Valve (FOV-DV7) Ventilation Adapter (AD-7) J Tube (JT-500) Air/Water button (AW-500) Suction button (SB-500) Water Jet Inlet cap
Optional Items		Same as K162622	Air leak tester LT-7F
Electrical Safety Compliance		**ANSI AAMI ES 60601-1 Edition 3.1**	ANSI AAMI ES 60601-1 Edition 3.0

Table 7.2 – Comparison Chart for EC-600LS

		Proposed Device	Predicate Device
Device name		EC-600LS	EC-600LS
Common name		Endoscope and accessories	Endoscope and accessories
Manufacturer		FUJIFILM Corporation	FUJIFILM Corporation
510(k) number		To be assigned	K162622
Intended Use/Indications for Use		Same as K162622	The 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.
Appearance		Same as K162622	
Viewing direction		Same as K162622	Forward / 0 degrees
Observation range		Same as K162622	2-100mm
Field of view		Same as K162622	170 degrees
F# of the objective lens		Same as K162622	7
Resolution		Same as K162622	At 5mm of working distance: 0.056mm of line pair on the square wave chart is readable. At 100mm of working distance: 1.25mm of line pair on the square wave chart is readable.
Distortion characteristics		Same as K162622	Orthogonal Projection
Magnification of lens(es)		Same as K162622	0.3-0.01
Focal length		Same as K162622	0.9mm
Image sensors		Same as K162622	CMOS
# of Light Guide Fiber Bundles		Same as K162622	2800
Distal end diameter		Same as K162622	11.5mm
Flexible portion diameter		Same as K162622	11.5mm
Maximum insertion diameter		Same as K162622	13.1mm
Bending capability	**Up**	Same as K162622	180 degrees
	Down	Same as K162622	180 degrees
	Left	Same as K162622	160 degrees
	Right	Same as K162622	160 degrees
Forceps channel diameter		Same as K162622	3.8mm
Working length		Same as K162622	1690mm
Total length		Same as K162622	1990mm

WJ Function	Same as K162622	available
Location of WJ inlet	Same as K162622	On the light guide connector
Video Processor	**Light source: BL-7000** **Processor: VP-7000** EPX-4440HD Light source: XL-4450 Processor: VP-4440HD **EPX-4440FN** **Light source: XL-4450FN** **Processor: VP-4440FN**	EPX-4440HD Light source: XL-4450 Processor: VP-4440HD
Video/Light guide connector	Same as K162622	500 Series
Peripherals	Same as K162622	Water Tank WT-2 Water Tank WT-4 Endoscopic Accessory (i.e. Forceps) Monitor Printer Electrosurgical Instruments Foot Switch Cart
Accessories	Same as K162622	Cleaning Brush (WB11002FW2) Cleaning Brush (WB5021FW2) Cleaning Adapter Kit (CA-510/A) Forceps Valve (FOV-DV7) Ventilation Adapter (AD-7) J Tube (JT-500) Air/Water button (AW-500) Suction button (SB-500) Water Jet Inlet cap
Optional Items	Same as K162622	Air leak tester LT-7F
Electrical Safety Compliance	**ANSI AAMI ES 60601-1 Edition 3.1**	ANSI AAMI ES 60601-1 Edition 3.0

Performance Data:

Fujifilm conducted the following performance testing on the proposed devices EC-600HL and EC-600LS to ensure that the modified devices perform equivalently to the predicate devices:

- Field of view
- Bending capability
- Air supply rate
- Water supply rate
- Suction rate
- Working length
- Forceps channel diameter
- Viewing direction

- Resolution
- LG output

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

Substantial Equivalence:

The company's EC-600HL and EC-600LS has the same intended use, indications for use, technological characteristics, and principles of operation as the previously cleared predicate EC-600HL and EC-600LS (K162622). The minor differences between the proposed devices and their predicate devices do not raise new or additional questions of safety or effectiveness of the proposed devices. Thus, the proposed devices EC-600HL and EC-600LS are substantially equivalent to their predicate devices.

Conclusions:

The modified EC-600HL and EC-600LS are substantially equivalent to the predicate EC-600HL and EC-600LS and conform to applicable medical device safety and performance standards.