August 3, 2018

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

Re: K180341
Trade/Device Name: FUJIFILM 600 Series Endoscope EG-600WR v2
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDS
Dated: July 5, 2018
Received: July 6, 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. 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,

Glenn B. Bell -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180341

Device Name
FUJIFILM 600 Series Endoscope EG-600WR v2

Indications for Use *(Describe)*
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.

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.

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510(k) SUMMARY

FUJIFILM 600 Series Endoscope EG-600WR v2

Submitter's Information:

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

Contact Person:

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Date Prepared: July 5th, 2018

Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM 600 Series Endoscope EG-600WR v2
Common Name:	Video Endoscope
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Classification:	Endoscope and accessories, 21 C.F.R. § 876.1500
Product Code:	FDS

Predicate Device:

Fujifilm 600 Series Endoscopes EC-600WL and EG-600WR, Fujifilm Medical Systems U.S.A, K132210

Reference Devices:

1. Fujifilm Video Colonoscope Model EC-600WLv2, FUJIFILM Medical Systems U.S.A., K160196
2. Fujifilm Endoscope Models EC-600HL and EC-600LS, FUJIFILM Medical Systems U.S.A., K162622

Intended Use / Indications for Use:

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.

Device Description:

FUJIFILM 600 Series Endoscope EG-600WR v2 is an upper gastrointestinal endoscope that captures 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 endoscope, 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:

The proposed device EG-600WR v2 differs from the predicate device in the following minor modifications:

- Use of a new epoxy resin in the manufacturing process instead of the original epoxy resin. Both the new and original epoxy resins can be used for repair.
- Minor design changes to the optical fiber, distal end cap, and air/water nozzle
- Addition of VP/BL-7000 (K163675) and VP-4440FN/XL-4450FN (K162836) as compatible video processors and light sources.
- Expansion of transport and storage conditions
- Use of an improved Air/Water button AW-500 and Suction button SB-500
- Continued compatibility with an improved Water Tank WT-4
- J Tube JT-500 is changed from a mandatory accessory to an optional accessory.

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

	Proposed Device	**Predicate Device**
Device name	EG-600WR v2	EG-600WR
Common name	Same as K132210	Endoscope and accessories
Manufacturer	Same as K132210	FUJIFILM Corporation
510(k) number	Same as K132210	K132210
Intended Use/Indications for Use	Same as K132210	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.

Appearance		Same as K132210	
Viewing direction		Same as K132210	Forward / 0 degrees
Observation range		Same as K132210	2-100mm
Field of view		Same as K132210	140 degrees
F# of the objective lens		Same as K132210	9.1
Resolution		Same as K132210	At 5mm of working distance: 0.07mm of line pair on the square wave chart is readable. At 100mm of working distance: 0.9mm of line pair on the square wave chart is readable.
Distortion characteristics		Same as K132210	Orthogonal Projection
Magnification of lens(es)		Same as K132210	0.48-0.01
Focal length		Same as K132210	1.2mm
Image sensors		Same as K132210	CMOS
# of Light Guide Fiber Bundles		Same as K132210	2800
Distal end diameter		Same as K132210	9.2mm
Flexible portion diameter		Same as K132210	9.3mm
Maximum insertion diameter		Same as K132210	10.7mm
Bending capability	**Up**	Same as K132210	210 degrees
	Down	Same as K132210	90 degrees
	Left	Same as K132210	100 degrees
	Right	Same as K132210	100 degrees
Forceps channel diameter		Same as K132210	2.8mm
Working length		Same as K132210	1100mm
Total length		Same as K132210	1400mm
WJ Function		Same as K132210	○
Location of WJ inlet		Same as K132210	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**	EPX-4440HD Light source: XL-4450 Processor: VP-4440HD

	Processor: VP-4440FN	
Video/Light guide connector	Same as K132210	500 Series
Peripherals	Same as K132210	Water Tank WT-2 Water Tank WT-4 Monitor Printer Electrosurgical Instruments Foot Switch Cart
Accessories	Cleaning Brush (WB11002FW2) Cleaning Brush (WB4321FW2) Cleaning Adapter Kit (CA-510/A) Forceps Valve (FOV-DV7) Ventilation Adapter (AD-7) Air/Water button (AW-500) Suction button (SB-500) Water Jet Inlet cap	Cleaning Brush (WB11002FW2) Cleaning Brush (WB4321FW2) 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	Air leak tester LT-7F J Tube (JT-500)	Air leak tester LT-7F
Electrical Safety Compliance	**ANSI AAMI ES60601-1 Edition 3.1**	ANSI AAMI ES60601-1 Edition 3.0

Substantial equivalence was determined based on the performance testing described below.

Performance Data:

Electrical safety testing was conducted on the proposed device EG-600WR v2 using the following consensus standards: ANSI/AAMI ES60601-1:2005+AMD1:2012 CSV, IEC 60601-1-2:2007, IEC 60601-1-6:2013, and IEC 60601-2-18:2009.

The proposed device EG-600WR v2 was adopted into biocompatibility testing conducted on the reference device EC-600WL v2 using the following consensus standards: ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

Endoscopic performance testing was conducted on the proposed device EG-600WR v2 according to the consensus standard ISO 8600-1:2015.

Cleaning, high-level disinfection, and sterilization validation testing was conducted on the proposed device EG-600WR v2 in accordance with the FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” (March 17, 2015).

The proposed device EG-600WR v2 was adopted into storage and transportation validation testing conducted on the reference devices EC-600HL/LS.

Fujifilm conducted the following performance testing on the proposed device EG-600WR v2 to ensure that the modified device performs equivalently to the predicate device:

- 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 device met the pre-defined acceptance criteria for the test.

Substantial Equivalence:

The company's EG-600WR v2 has the same intended use as the previously cleared predicate EG-600WR (K132210). In addition, the proposed device EG-600WR v2 has similar indications for use, technological characteristics, and principles of operation as its predicate. The minor differences between the proposed device and its predicate device do not raise new or additional questions of safety or effectiveness of the proposed device. Thus, the proposed device EG-600WR v2 is substantially equivalent to its predicate device.

Conclusions:

The modified EG-600WR v2 is substantially equivalent to the predicate EG-600WR and conforms to applicable medical device safety and performance standards.