



Food and Drug Administration
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February 23, 2016

Fujifilm Medical Systems USA, Inc.
% John Smith, MD, JD
Partner
Hogan Lovells US LLP
555 Thirteenth St. NW
Washington, DC 20004

Re: K160196
Trade/Device Name: Fujifilm Video Colonoscope Model EC-600WL v2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FDF
Dated: January 27, 2016
Received: January 27, 2016

Dear Dr. Smith,

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 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

Indications for Use

510(k) Number (if known)

K160196

Device Name

FUJIFILM Video Endoscope Model EC-600WL v2

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.

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510(k) SUMMARY

Fujifilm's EC-600WL v2

Submitter's Information

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Endoscopy Division
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Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

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Date Prepared: January 27, 2016

Identification of the Subject Device:

Proprietary/Trade Name:	Fujifilm Video Colonoscope Model EC-600WL v2
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 600 series colonoscope EC-600WL (K132210)

Purpose of the Special 510(k) notice.

The EC-600WL v2 is a modification to EC-600WL.

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.

Technological Characteristics

The Fujifilm video colonoscope model EC-600WL v2 is a modified version of the legally marketed Fujifilm Colonoscope EC-600WL in K132210. Just like K132210, the proposed EC-600WL v2 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 EC-600WL v2 is 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 EC-600WL v2 is 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 minor modifications to the proposed device were made for the purpose of overall product enhancement and general technological advancement.

Performance Data

Fujifilm conducted the following performance testing of the EC-600WL v2 to ensure that the modified device performs equivalently to the predicate EC-600WL:

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

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

Substantial Equivalence

EC-600WL v2 has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate EC-600WL. The minor differences in the modified device's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the EC-600WL v2 is as safe and effective as EC-600WL. Thus, the EC-600WL v2 is substantially equivalent to its predicate device.