DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 13, 2017

Fujifilm New Development U.S.A., Inc.
% Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, Massachusetts 01864

Re: K162836
Trade/Device Name: Fujifilm Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 23, 2017
Received: February 24, 2017

Dear Ms. O'Connell:

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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K162836

Device Name
FUJIFILM Surgical System

Indications for Use *(Describe)*
The FUJIFILM Surgical System includes a laparoscope, video processor and light source and is intended to be used with a monitor, hand instruments, electrosurgical unit, and other ancillary equipment for minimally invasive laparoscopic observation, diagnosis and treatment in general abdominal and gynecologic areas.

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 New Development U.S.A, Inc.
FUJIFILM Surgical System

510(k) Owner

FUJIFILM New Development U.S.A, Inc.
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Contact Person: Stephen Mariano

Submission Correspondent:

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Date Prepared:October 6, 2016

Trade Name of Device
FUJIFILM Surgical System

Common or Usual Name
Laparoscope and Video Processor

Classification Name
Endoscope and Accessories; 21 C.F.R. 876.1500
Class II
Product Code: GCJ

Predicate Devices
Fujinon, Inc. EL2-TF410 Video Laparoscope (K983561)
FUJIFILM Corp. EPX-4440 HD Digital Video Processor with FICE (K140149)

Device Description
The FUJIFILM Surgical System is comprised of:

- EL-580FN Video Laproscope with RC-4440FN Relay Connector
- EPX-4440FN Digital Video Processor with light source
    - VP-4440FN Video Processor
    - XL-4450FN Light Source
    - DK-4440E Data Keyboard

The EL-580FN Video Laparoscope is comprised of a rigid insertion portion, cable portion, video connector and light guide connector. An optical system, CCD image sensor and electrical circuits are located within the distal end portion of the laparoscope. The video signal lines from the CCD sensor and the light guide fiber bundles are connected to the video connector and light guide connector respectively through the laparoscope and video cables.

The EL-580FN Video Laparoscope is used with the EPX-4440FN Digital Video processor which consists of the VP-4440FN Processor and the XL-4450FN Light Source. The video connector is connected to the video processor via the RC-4440FN Relay Connector and the light connector is connected to the XL-4450FN Light Source. The VP-4440FN Video Processor relays the image from a laparoscope to a video monitor. The processor also controls the light projected to the body cavity. The XL-4450FN Light Source employs a Xenon lamp with an emergency back-up Halogen lamp. Brightness control is performed by the user.

Intended Use / Indications for Use

The FUJIFILM Surgical System includes a laparoscope, video processor and light source and is intended to be used with a monitor, hand instruments, electrosurgical unit, and other ancillary equipment for minimally invasive laparoscopic observation, diagnosis and treatment in general abdominal and gynecologic areas.

Substantial Equivalence

The FUJIFILM Surgical System is substantially equivalent to Fujinon, Inc.'s EL2-TF410 Video Laparoscope cleared in K983561 and FUJIFILM's EPX-4440 HD Digital Video Processor with FICE cleared in K140149 ("the predicate devices"). The FUJIFILM Surgical System has the same intended use, principles of operation, and similar technological characteristics as the previously cleared predicate devices.

The FUJIFILM Surgical System includes a laparoscope, video processor and light source while the predicate devices were cleared in two separate 510(k)s. Fujinon, Inc.'s EL2-TF410 Video Laparoscope is also intended for use during minimally invasive laparoscopic observation, diagnosis and treatment. FUJIFILM's EPX-4440 HD Digital Video Processor with FICE is intended for observation, diagnosis, treatment, and image recording by processing electronic signals transmitted from a video endoscope. All of these devices are prescription devices used by healthcare professionals.

Although the subject devices and predicate devices are very similar, there are minor differences in the technological characteristics of the devices. The FUJIFILM Surgical System is comprised of a video laparoscope and a video processor with light source. The video laparoscope has similar technological characteristics to the EL2-TF410 Video Laparoscope in that both consist of a rigid portion, cable portion, image connector and light connector. Identical characteristics include direction of view, image sensor type, resolution, and sterility requirements. Each difference between the subject device and predicate device has been evaluated and determined not to raise new questions of safety or effectiveness.

The VP-4440FN Video Processor and XL-4450FN Light Source have the same technological characteristics as the EPX-4440 HD Digital Processor with FICE also made by FUJIFILM. Both systems have a Xenon lamp as the main lamp with a Halogen lamp as the emergency lamp. All technical specifications relevant to the indications for use of the subject device and predicate device are identical.

Performance testing was performed which compared the subject and predicate devices and demonstrates substantial equivalence. Therefore, the FUJIFILM Surgical System is substantially equivalent to the predicate devices.

Performance Data

Bench testing was conducted in order to demonstrate compliance with recognized consensus standards:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007: Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility -Requirements and tests
- IEC 60601-2-18 Edition 3.0 2009-08 Medical electrical equipment-Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 10993-1:2009 Biological evaluation of medical devices. Evaluation and testing within a risk management process.
- AAMI ANSI ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
- ISO 10993-11: Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
- ISO 8600-1 Fourth edition Optics and photonics-Medical endoscopes and endotherapy devices-Part 1: General requirements
- ISO 8600-3 First edition 1997-07-01 Optics and optical instruments - Medical endoscopes and endoscope accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics (Including: Amendment 1 (2003)
- ISO 8600-4 Second edition 2014-03-15 Optics and optical instruments-Medical endoscopes and certain accessories-Part 4: Determination of maximum width of insertion portion
- ISO 8600-5 First Edition 2005-03-15 Optics and photonics - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics
- ISO 8600-6 First edition 2005-03-15 Optics and photonics - Medical endoscopes and endotherapy devices - Part 6: Vocabulary

- ISO 14971:2007, Medical Device Risk Management-Part 1: Application of risk management to medical devices
- IEC 62471: 2006 Photobiological safety of lamps and lamp systems
- AAMI ANSI IEC 62304:2006 Medical device software. Software lifecycle processes.

Additionally, performance criteria were compared between the subject device and the predicate device and the predicate device was determined to be substantially equivalent to the predicate. The EL-580FN Video Laparoscope and the predicate device, the Fujinon EL2-TF410 Laparoscope (K983561) met all the acceptance criteria. Substantial equivalence of the two devices was demonstrated in terms of the technological characteristics.

The conclusions drawn from the non-clinical testing demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.