May 24, 2018

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

Re: K180414
Trade/Device Name: EPX-4440FN Digital Video Processor with Light Source
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FET, GCT, PEA
Dated: April 9, 2018
Received: April 10, 2018

Dear Maureen 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.

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,

Joyce M. Whang -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180414

Device Name
EPX-4440FN Digital Video Processor with Light Source

Indications for Use *(Describe)*
The EPX-4440FN Digital Video Processor with Light Source is used for endoscopic or laparoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope or laparoscope (a video camera in an endoscope or laparoscope). This product may be used on all patients requiring endoscopic examination or laparoscopic surgical procedures and when using a FUJIFILM medical endoscope or laparoscope, light source, monitor, recorder and various peripheral devise. FICE (Flexible spectral-Imaging Color Enhancement) is an adjunctive tool for gastrointestinal endoscopic examination which can be used to supplement FUJIFILM white light endoscopy. FICE is not intended to replace histopathologic sampling as a means of diagnosis.

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.
EPX-4440FN Digital Video Processor with Light Source

510(k) Owner

FUJIFILM New Development U.S.A, Inc.

318 Bear Hill Road

Waltham, MA 02451
Phone: 781-860-2463
Contact Person: Stephen Mariano

Submission Correspondent:

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Phone: 978-207-1245

Date Prepared: February 9, 2018

Trade Name of Device

EPX-4440FN Digital Video Processor with Light Source

Common or Usual Name

Video Processor and Light Source

Regulation Name

Endoscope and Accessories; 21 C.F.R. 876.1500
Class II
Product Code: FET, GCT and PEA

Predicate Devices

FUJIFILM New Development U.S.A., Inc. FUJIFILM Surgical System (K162836)

FUJIFILM Corp. EPX-4440HD Digital Video Processor with FICE and Light Source (K140149)

Device Description

The EPX-4440FN Digital Video Processor with Light Source is comprised of:

- VP-4440FN Video Processor with DK-4440E Data Keyboard
- XL-4450FN Light Source

The EPX-4440FN Digital Video Processor with Light Source consists of the VP-4440FN Video Processor and the XL-4450FN Light Source. The VP-4440FN Video Processor relays

the image from a laparoscope or endoscope 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 EPX-4440FN Digital Video Processor with Light Source is used for endoscopic or laparoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope or laparoscope (a video camera in an endoscope or laparoscope). This product may be used on all patients requiring endoscopic examination or laparoscopic surgical procedures and when using a FUJIFILM medical endoscope or laparoscope, light source, monitor, recorder and various peripheral devices. FICE (Flexible spectral-Imaging Color Enhancement) is an adjunctive tool for gastrointestinal endoscopic examination which can be used to supplement FUJIFILM white light endoscopy. FICE is not intended to replace histopathological sampling as a means of diagnosis.

Substantial Equivalence

The EPX-4440FN Digital Video Processor with Light Source is substantially equivalent to the FUJIFILM New Development U.S.A., Inc. FUJIFILM Surgical System cleared in K162836 and FujiFilm's EPX-4440 HD Digital Video Processor with FICE and Light Source cleared in K140149 ("the predicate devices"). The intended use of the EPX-4440FN Digital Video Processor with Light Source is for endoscopic or laparoscopic observation, diagnosis, treatment and image recording. The FUJIFILM Surgical System is intended for use in laparoscopic observation, diagnosis, and treatment while the FUJIFILM EPX-4440 HD Digital Video Processor with FICE and Light Source is intended for use in endoscopic observation, diagnosis, treatment, and image processing. All of these devices are prescription devices used by healthcare professionals.

The devices have the same technological characteristics. The EPX-4440FN Digital Video Processor with Light Source is comprised of the VP-4440FN Video Processor, XL-4450FN Light Source and DK-4440E Data Keyboard which are the same components included in the FUJIFILM Surgical System cleared in K162836. The system cleared in K162836 also included a laparoscope while this system is for use with both a laparoscope or an endoscope. The FUJIFILM EPX-4440 HD Digital Video Processor with FICE and Light Source is comprised of the VP-4440 HD Video Processor, the XL-4450 Light Source and the DK-4440E Data Keyboard.

The VP-4440FN Digital Video Processor with XL-4450FN Light Source has the same technological characteristics as the EPX-4440 HD Digital Processor with FICE and Light Source also made by FUJIFILM and cleared in K140149 for use with an endoscope. 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.

Therefore, based on the devices having the same intended use and the same technological characteristics the EPX-4440FN Digital Video Processor with Light Source 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 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 testing showed that the EPX-4440FN Digital Video Processor with Light Source met all the acceptance criteria.

The conclusions drawn from the non-clinical testing demonstrate that the device is as safe and effective as the legally marketed predicate device.