May 1, 2020

FUJIFILM Corporation
% Candace Alva
Director, Quality Management Systems
FujiFilm Medical Systems U.S.A., Inc.
81 Hartwell Avenue
Lexington, MA 02421

Re: K192286
Trade/Device Name: FUJIFILM EP-6000 Video Processor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET, NTN, NWB, PEA, EOQ
Dated: August 20, 2019
Received: August 22, 2019

Dear Candace Alva:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*

K192286

Device Name

FUJIFILM Video Processor EP-6000

Indications for Use *(Describe)*

The EP-6000 is an endoscopic processor with an integrated light source that is intended to provide illumination, process electronic signals transmitted from a video endoscope and enable image recording. This product can be used in combination with compatible medical endoscope, a monitor, a recorder and various peripherals. It supplies air through the endoscope, for obtaining clear visualization and is used for endoscopic observation, diagnosis and treatment.

BLI (Blue Light Imaging), LCI (Linked Color Imaging) and FICE (Flexible spectral-Imaging Color Enhancement) are adjunctive tools for gastrointestinal endoscopic examinations which can be used to supplement Fujifilm white light endoscopy. BLI, LCI and FICE are not intended to replace histopathological sampling as a means of diagnosis. BLI, LCI, and FICE are not intended for bronchoscopic examination.

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 Corporation's
FUJIFILM Video Processor EP-6000

Date: April 30, 2020

Submitter's Information:

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

Contact Person:

Candace Alva
Director, Quality Management Systems
Telephone: (828) 638-5240
E-Mail: candace.alva@fujifilm.com

Identification of the Proposed Devices:

Proprietary/Trade Name:	FUJIFILM Video Processor EP-6000
Common Name:	Endoscopic Video Imaging System
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Classification Information:

Classification Name	CFR Section	Product Codes
Endoscope and accessories	21 CFR 876.1500	FET, NTN, NWB, PEA, EOQ

Predicate Device:

- FUJIFILM Video Processor VP-7000 and Light Source BL-7000 (K163675)

Intended Use / Indications for Use

The EP-6000 is an endoscopic processor with an integrated light source that is intended to provide illumination, process electronic signals transmitted from a video endoscope and enable image recording. This product can be used in combination with compatible medical endoscope, a monitor, a recorder and various peripherals. It supplies air through the endoscope, for obtaining clear visualization and is used for endoscopic observation, diagnosis and treatment.

BLI (Blue Light Imaging), LCI (Linked Color Imaging) and FICE (Flexible spectral-Imaging Color Enhancement) are adjunctive tools for gastrointestinal endoscopic examinations which can be used to supplement Fujifilm white light endoscopy. BLI, LCI and FICE are not intended to replace histopathological sampling as a means of diagnosis. BLI, LCI, and FICE are not intended for bronchoscopic examination.

Device Description

FUJIFILM Video Processor EP-6000 relays the image from an endoscope to a video monitor. The projection can be either analog or digital at the user's preference. The processor incorporates internal or external digital storage capacity. The processor employs fiber bundles to transmit light from three LED lamps, with a total power of 59.5W, to the body cavity. Brightness control is performed by the user. The processor provides for optional structural enhancement through user modes FICE, BLI, BLI-bright and LCI. Spectral and structural enhancements are achieved through proprietary software. The device is AC operated at a power setting of 100-240V/50-60Hz/2.0-1.1A. The processor is housed in a steel-polycarbonate case measuring 395x210x485mm.

Comparison of Technological Characteristics

FUJIFILM Video Processor EP-6000 differs from the predicate devices VP-7000 and BL-7000 in terms of technological characteristics. The subject and predicate devices share the same mode of operation and intended use.

A summary of major differences between the subject device EP-6000 and the predicate devices VP-7000 and BL-7000 is provided as follows:

- One unit that provides both video processing and light sourcing functions
- Number of LED lamps used for light transmission

Performance Data

Electrical, laser, and photobiological safety of the subject device was evaluated using the following standards: ANSI/AAMI ES 60601-1: 2005/(R)2012 and A1:2012, IEC 60601-1-2:2014, IEC 60601-2-18:2009, IEC 60825-1:2007, and IEC 62471:2006.

Software validation was evaluated in accordance with ANSI/AAMI/IEC 62304:2006 and the FDA guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” published May 11, 2005. Cybersecurity controls were developed according to the FDA guidance, “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,” published October 2, 2014.

Functional testing of the various image processing modes included Color Reproduction and Color Contrast Enhancement. All testing criteria were met, and the device functioned as intended in all instances.

Substantial Equivalence

The subject device FUJIFILM Video Processor EP-6000 is substantially equivalent to the predicate devices, FUJIFILM Video Processor VP-7000 and Light Source BL-7000 (K163675). The subject and predicate devices share the same intended use and substantially similar indications. Bench testing demonstrates that the differences in technological characteristics raise no new issues of safety or effectiveness. Thus, EP-6000 is substantially equivalent to the predicate devices.

Conclusions

The subject device FUJIFILM Video Processor EP-6000 is substantially equivalent to the predicate devices based on the same intended use, similar indications for use, and similar technological characteristics.