February 20, 2020

FUJIFILM Corporation
% Jeffrey Wan
Senior Regulatory Affairs Specialist
FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Avenue, Suite 300
Lexington, Massachusetts 02421

Re: K192918
Trade/Device Name: FUJIFILM Video Laparoscope EL-R740S, Video Processor VP-7000, Light Source BL-7000
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, FET, NTN, NWB, PEA
Dated: January 24, 2020
Received: January 27, 2020

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/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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K192918

Device Name
FUJIFILM Video Laparoscope EL-R740S, Video Processor VP-7000, and Light Source BL-7000

Indications for Use *(Describe)*
FUJIFILM Video Laparoscope EL-R740S is intended to be used with a video processor, light source, monitor, hand instruments, electrosurgical unit and other ancillary equipment for minimally invasive observation, diagnosis and treatment in general abdominal, gynecologic and thoracic areas.

The VP-7000 unit is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope). This product may be used on all patients requiring endoscopic examination and when using a Fujinon/FUJIFILM medical endoscope and light source together with monitor, recorder and various peripheral devices. BLI (Blue Light Imaging), LCI (Linked Color Imaging) and FICE (Flexible spectral-Imaging Color Enhancement) are adjunctive tools for gastrointestinal endoscopic examination 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.

The BL-7000 Light Source is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to provide illumination to an endoscope. The light source also functions as a pump to supply air through the endoscope while inside the body to assist in obtaining clear visualization to facilitate diagnostic examination. This product may be used on all patients requiring endoscopic examination and when using a Fujinon/FUJIFILM medical endoscope and video processor together with monitor, recorder and various peripheral devices.

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 Corporation's
Video Laparoscope EL-R740S, Video Processor VP-7000, and Light Source BL-7000

Date: October 11, 2019

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

Contact Person:
Jeffrey Wan
Senior Regulatory Affairs Specialist
Telephone: (201) 675-8947
E-Mail: jeffrey.wan@fujifilm.com

Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM Video Laparoscope EL-R740S, Video Processor VP-7000, and Light Source BL-7000
Common Name:	Laparoscope, Endoscopic Video Imaging System, LED Light Source
Device Class:	Class II
Review Panel:	General & Plastic Surgery

Classification Information:

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

Predicate Device:

- EL-580FN Video Laparoscope (K162836)
- FUJIFILM Video Processor VP-7000 and Light Source BL-7000 (K163675)

Reference Device:

- VP-4440FN Video Processor and XL-4450FN Light Source (K180414)
- FUJIFILM Endoscope Model EG-740N (K182836)
- EL2-TF410 Video Laparoscope (K983561)

Intended Use / Indications for Use

FUJIFILM Video Laparoscope EL-R740S is intended to be used with a video processor, light source,

monitor, hand instruments, electrosurgical unit and other ancillary equipment for minimally invasive observation, diagnosis and treatment in general abdominal, gynecologic and thoracic areas.

The VP-7000 unit is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope). This product may be used on all patients requiring endoscopic examination and when using a Fujinon/FUJIFILM medical endoscope and light source together with monitor, recorder and various peripheral devices. BLI (Blue Light Imaging), LCI (Linked Color Imaging) and FICE (Flexible spectral-Imaging Color Enhancement) are adjunctive tools for gastrointestinal endoscopic examination 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.

The BL-7000 Light Source is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to provide illumination to an endoscope. The light source also functions as a pump to supply air through the endoscope while inside the body to assist in obtaining clear visualization to facilitate diagnostic examination. This product may be used on all patients requiring endoscopic examination and when using a Fujinon/FUJIFILM medical endoscope and video processor together with monitor, recorder and various peripheral devices.

Device Description

Video Laparoscope EL-R740S is comprised of a rigid insertion portion, cable portion, and scope 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 scope connector through the laparoscope.

Video Processor VP-7000 relays the image from the endoscope to a video monitor. Projection can be either analog or digital at the user's preference. The Processor incorporates internal or external digital storage capacity. VP-7000 also controls the light projected to the body cavity. VP-7000 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/0.8-0.5A. VP-7000 is housed in a steel polycarbonate case measuring 390x110x485mm.

The Fujinon/FUJIFILM endoscope employs fiber bundles to transmit light from Light Source BL-7000 to the body cavity. BL-7000 employs 4 LED lamps with a total power of 79.2W. Brightness control is performed by the user. The device is AC operated at a power setting of 100-240V/50-60Hz/1.2- 0.7A. BL-7000 is housed in a steel polycarbonate case measuring 390x155x485mm.

Comparison of Technological Characteristics

Video Laparoscope EL-R740S, Video Processor VP-7000, and Light Source BL-7000 differ from the predicate devices 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 and predicate devices is provided as follows:

Video Laparoscope EL-R740S

- Additional indication in the thoracic area
- Compatibility with VP-7000 and BL-7000
- Software is added to accommodate contactless optical communication to BL-7000.
- Material changes to the insertion portion

Video Processor VP-7000 and Light Source BL-7000

- Compatibility with FUJIFILM R700 system scopes
- Compatibility with optional camera control units
- Software update to accommodate compatibility with R700 system scopes and other camera control units

Performance Data

Electrical, laser, and photobiological safety of the subject device was evaluated using following standards: ANSI/AAMI ES60601-1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2013, IEC 60601-2-18:2009, IEC 60825-1:2007, and IEC 62471:2006.

Biocompatibility of the subject device was evaluated using the following consensus standards: ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, and ISO 10993-11:2017. Biocompatibility testing was performed in accordance with FDA's guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" published June 16, 2016.

Endoscope specific testing was conducted according to ISO 8600-1:2015.

Validation of the cleaning and sterilization instructions for the proposed device EL-R740S was performed in accordance with FDA's guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," published March 17, 2015.

Software testing was conducted according to 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.

The subject device was evaluated for color reproduction and image resolution. In both cases, the subject device demonstrated substantial equivalence to the predicate device.

Substantial Equivalence

The subject devices FUJIFILM Video Laparoscope EL-R740S, Video Processor VP-7000, and Light Source BL-7000 are substantially equivalent to the predicate devices, EL-580FN Video Laparoscope (K162836), 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 and materials raise no new issues

of safety or effectiveness. Thus, FUJIFILM Video Laparoscope EL-R740S, Video Processor VP-7000, and Light Source BL-7000 are substantially equivalent to the predicate devices.

Conclusions

The subject devices Video Laparoscope EL-R740S, Video Processor VP-7000, and Light Source BL-7000 are substantially equivalent to the predicate devices based on the same intended use, similar indications for use, and substantially equivalent technological characteristics and materials.