June 30, 2021

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

Re: K203717
Trade/Device Name: Processor VP-7000, Light Source BL-7000X, Image Processing Unit EX-0
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, FET, NTN, PEA, MUD, NWB
Dated: June 29, 2021
Received: June 29, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203717

Device Name
FUJIFILM Processor VP-7000, Light Source BL-7000X, and Image Processing Unit EX-0

Indications for Use *(Describe)*
Processor VP-7000:

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 Image Processing Unit EX-0 is an optional module intended for use as an adjunctive monitor of the hemoglobin oxygen saturation of blood in superficial tissue of the endoscopic observation image area in patients at risk for ischemic states.

This product may be used on all patients requiring endoscopic examination when using a Fujinon/FUJIFILM medical endoscope, video processor and light source together with monitor, recorder and various peripheral devices.

The prospective clinical value of measurements made with OXEI has not been demonstrated in disease states.

Light Source BL-7000X:

The BL-7000X 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
FUJIFILM Corporation
Processor VP-7000, Light Source BL-7000X, and Image Processing Unit EX-0

Date: June 30, 2021

Submitter's Information:
FUJIFILM Corporation
798 Miyanodai Kaisei-Machi
Ashigarakami-Gun, Kanagawa, Japan 258-8538

Contact Person:
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Manager, Regulatory Affairs
Telephone: (201) 675-8947
E-Mail: jeffrey.wan@fujifilm.com

Identification of the Subject Device:

Device Name:	Processor VP-7000, Light Source BL-7000X, Image Processing Unit EX-0
Common Name:	Endoscopic Video Imaging System/Component
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 876.1500
Device Class:	Class II
Classification Product Code:	GCJ
Subsequent Product Codes:	MUD, FET, NTN, NWB, PEA

Predicate Device:

- FUJIFILM Video Processor VP-7000 and Light Source BL-7000 (K192918)

Reference Device:

- T-Stat 303 Microvascular Tissue Oximeter (K081233)

Intended Use / Indications for Use

VP-7000
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 Image Processing Unit EX-0 is an optional module intended for use as an adjunctive monitor of the hemoglobin oxygen saturation of blood in superficial tissue of the endoscopic observation image area in patients at risk for ischemic states.

This product may be used on all patients requiring endoscopic examination when using a Fujinon/FUJIFILM medical endoscope, video processor and light source together with monitor, recorder and various peripheral devices.

The prospective clinical value of measurements made with OXEI has not been demonstrated in disease states.

BL-7000X
The BL-7000X 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

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. VP-7000 also incorporates internal or external digital storage capacity. VP-7000 controls the light projected to the body cavity. VP-7000 provides for optional structural enhancement through user modes FICE (Flexible spectral-Imaging Color Enhancement), BLI (Blue Light Imaging), BLI-brt (Blue Light Imaging-Bright) and LCI (Linked Color Imaging) at the user's option. Spectral and structural enhancements are achieved through proprietary software. The device is AC operated at a power setting of 120V/60Hz, 0.8A. VP-7000 is housed in a steel-polycarbonate case measuring 390x485x110mm. Optional Image Processing Unit EX-0 receives image data from the VP-7000, and displays an OXEI image on a LCD monitor. The OXEI image is a color-coded digital image showing tissue oxygen saturation (StO2). EX-0 incorporates an internal digital storage capacity. The device is AC-operated at a power setting of 120V/60Hz, 1.0A. EX-0 is housed in a steel-polycarbonate case measuring 320x165x340 mm.

The Fujifilm endoscopes employ fiber bundles to transmit light from Light Source BL-7000X and subsequently to the body cavity. BL-7000X employs five LED lamps. Brightness control is performed by the user. The device is AC operated at a power setting of 120V / 60Hz 1.2A. BL-7000X is housed in a steel polycarbonate case measuring 395x485x155mm.

Processor VP-7000, Light Source BL-7000X, and Image Processing Unit EX-0 are used as a system in conjunction with a compatible video laparoscope or endoscope for visualization of tissue oxygen saturation (StO2) levels.

Comparison of Technological Characteristics

A comparison of the technological characteristics between the subject and predicate devices is provided below, as well as a comparison of the technological characteristics of the subject device to a reference device:

	Subject Device	**Predicate Device**	**Equivalence**
Manufacturer	FUJIFILM Corporation	FUJIFILM Corporation	
Device Name	Processor VP-7000	FUJIFILM Processor VP-7000	
510(k) Number	K203717	K192918	
Indications for Use	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 Image Processing Unit EX-0 is an optional module intended for use as an adjunctive monitor of the hemoglobin oxygen saturation of blood in superficial tissue of the endoscopic observation image area in patients at risk for ischemic states. This product may be used on all patients requiring endoscopic examination when using a Fujinon/FUJIFILM medical endoscope, video processor and light source together with monitor, recorder and various peripheral devices. The prospective clinical value of measurements made with OXEI has not	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.	Both of the subject and predicate VP-7000 are specifically indicated for observation, diagnosis, treatment and image recording. The addition of ability to adjunctively monitor hemoglobin oxygen saturation of blood in superficial issue of the endoscopic observation image area in patients at risk for ischemic states is consistent with the observational and diagnostic intended use and does not raise different questions of safety or effectiveness.

	been demonstrated in disease states.		
Power Rating	100-240V AC; 50/60Hz; 0.8-0.5A;	100-240V AC; 50/60Hz; 0.8-0.5A;	Identical
FICE mode	Yes	Yes	Identical
BLI mode	Yes	Yes	Identical
BLI-bright mode	Yes	Yes	Identical
LCI mode	Yes	Yes	Identical
OXEI (Oxygen Saturation Information)	Two-dimensional, color-coded images of StO2% of the endoscopic observation image area	Not available	Equivalent
Dimensions WxHxD mm	390x110x485 mm	390x110x485 mm	Identical
Weight	9 kg	9 kg	Identical

	Subject Device	**Predicate Device**	**Equivalence**
Manufacturer	FUJIFILM Corporation	FUJIFILM Corporation	
Device Name	Light Source BL-7000X	FUJIFILM Light source BL-7000	
510(k) Number	K203717	K192918	
Indications for Use	The BL-7000X 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	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.	Equivalent
Power Rating	100-240V AC; 50/60Hz; 1.2-0.7A;	100-240V AC; 50/60Hz; 1.2-0.7A;	Identical
Lamp	5 LED lamps	4 LED lamps	Equivalent
Dimensions WxHxD mm	395x485x155 mm	390x485x155 mm	Identical
Weight	16 kg	12 kg	Equivalent

Performance Data

Software:

Software of the subject device was evaluated according to IEC 62304:2015 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.

Electrical Safety/Electromagnetic Compatibility:

Electrical safety, electromagnetic compatibility, and laser safety of the subject device were evaluated using the following standards: ANSI/AAMI ES 60601-1: 2005/(R)2012 and A1:2012, IEC 60601-1- 2:2014, IEC 60601-1-6:2013, IEC 60601-2-18:2009, and IEC 60825-1:2007.

Photobiological safety of the subject device was evaluated according to IEC 62471:2006. The subject device met all exposure limits and was found to not pose a realistic optical hazard.

Performance Testing:

The StO_2 measurement function was evaluated via comparative bench testing and animal testing.

- Bench testing:

  StO2 measurement performance of the subject and reference devices was compared with a dissolved oxygen meter as a gold standard using 7 different blood-based phantoms, simulating the optical properties of different tissues that may be monitored by the subject device. The subject device was used in combination with the Video Laparoscope EL-R740M, Endoscope EC-740T/L and EG-740N to measure the StO2 level. Results demonstrated that the subject device performs comparably to the reference device, T-Stat (K081233), with respect to monitoring StO2 levels.

- Animal Testing: Three animal studies were conducted: one laparoscopic (Study 1), one endoscopic (Study 2) and one for open surgery (Study 3).

  Study 1: A visualization study was conducted to measure the tissue oxygenation saturation (StO2). This study used the subject and reference devices in a laparoscopic manner to look at the serosal surface of the stomach, small intestine, and large intestine. The variability between the subject and reference devices was approximately 29.8%, potentially due to the StO2 variability within the observed tissues. Variability in these measurements has also been reported in the literature. Additionally, limited images were provided to be able to assess the visualization of the device. However, adequate images were provided from this study to show visualization of the device, as well as the StO2 overlay, which were considered acceptable.

  Two additional animal studies addressed this variability in oxygenation.

Study 2: Tissue oxygen saturation (StO2) in the large intestine and stomach for mucosal tissue was measured endoscopically in 4 female Göttingen minipigs at 11 months of age under general anesthesia with decreased arterial oxygen saturation (SpO2) from 100% to 60%. A correlation of the results with the reference device was compared for performance evaluation. Comparative StO2 measurement performance was evaluated in the swine to simulate clinically-relevant usage of the subject and reference devices. The results of this study demonstrated that the subject device could monitor/measure StO2 levels in a clinically relevant setting.

Study 3: Comparative StO2 measurement performance was evaluated when the subject and reference devices measured StO2 at the same locations under controlled conditions in the open surgery setting where the abdomen was incised and the tissues were exposed and fixed to minimize tissue movement. The StO2 measurement was performed at five parts of the GI tract of each of the three swine including the serosal surface of the stomach, small intestine, and large intestine and the mucosal surface of the stomach and large intestine. Difference in the StO2 readings between the subject and reference devices were analyzed at each part. Measurements of the StO2 were evaluated by the subject and reference devices, which has differences up to 11.4%. The results of this study demonstrated that the subject device measures/monitors the StO2 comparably to the reference device, similar to the bench testing.

The combination of these three studies established that the EX-0 device may be used as an adjunctive monitor of the hemoglobin oxygenation saturation of blood in superficial tissue.

Conclusions

The subject devices FUJIFILM Processor VP-7000, Light Source BL-7000X, and Image Processing Unit EX-0 share the same intended use and substantially similar indications to the predicate device. Bench and animal testing demonstrate that the subject devices are as safe and effective as the predicate device. Thus, FUJIFILM Processor VP-7000, Light Source BL-7000X, and Image Processing Unit EX-0 are substantially equivalent to the listed predicate device.