



Food and Drug Administration
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April, 25, 2017

FUJIFILM Medical System U.S.A., Inc.
Shraddha S More
Specialist, Regulatory Affairs
and Quality Assurance
10 High Point Drive
Wayne, NJ 07470

Re: K163675
Trade/Device Name: FUJIFILM Processor VP-7000 and Light source BL-7000
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Codes: FET, NTN, NWB, PEA
Dated: March 21, 2017
Received: March 21, 2017

Dear Shraddha S More:

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,


Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)

K163675

Device Name

FUJIFILM Processor VP-7000 and Light source BL-7000

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.

Light Source BL-7000

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 Processor VP-7000 and Light Source BL-7000

Date: March 21, 2017

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.,
Endoscopy Division
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Person:

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Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM Processor VP-7000 and Light Source BL-7000
Common Name:	Endoscopic Video Imaging System/Component
Device Class:	Class II
Review Panel:	Gastroenterology and Urology

Classification Information:

Classification Name	CFR Section	Product Codes
Endoscopic Video Imaging System/Component, Gastroenterology- Urology	21 CFR 876.1500	FET
Led Light source, Endoscope and accessories	21 CFR 876.1500	NTN
Endoscope and accessories, Narrow Band Spectrum	21 CFR 876.1500	NWB
Endoscope, Accessories, Image Post-Processing For Color Enhancement	21 CFR 876.1500	PEA

Predicate Device

- Primary: Fujifilm EPX-4440HD Digital Video Processor with FICE and Light Source (K140149)
- Secondary: Olympus Video System Center CV-170 (K122831)

Device Description

VP-7000 and BL-7000 are intended to be used in conjunction with Fujinon/FUJIFILM endoscopes for endoscopic observation, diagnosis, treatment, and image recording. The description for each of the components of the subject device is below:

The VP-7000 Video Processor:

The Processor 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. The Processor also controls the light projected to the body cavity. 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/0.8-0.5A. The Processor is housed in a steel-polycarbonate case measuring 390x110x485mm.

The DK-7000E Keyboard is a standard accessory of VP-7000. It is used to enter pertinent procedural information (patient, physician, date, etc.) for display on the video monitor and digital/analog storage systems. The Keyboard is also used to control operational features of the VP-7000 Processor. The Keyboard resembles a standard computer keyboard, and is provided with an instruction label attached to it.

The BL-7000 Light Source:

The Fujinon/FUJIFILM endoscope employs fiber bundles to transmit light from the light source and subsequently to the body cavity. The Light Source employs 79.2W 4 LED lamps. 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. The Light Source is housed in a steel-polycarbonate case measuring 390x155x485mm.

Intended Use / Indications for Use

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.

Light Source BL-7000

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.

Summary of Technological Characteristics

The differences between the technological characteristics of the subject device and predicate devices are provided in the table below.

VP-7000 and BL-7000 are the same as the cleared EPX-4440HD Digital Video Processor with FICE and Light source (K140149) device, with the exception of additional image processing options termed as “BLI” (Blue Light Imaging) and LCI (Linked Color Imaging) for providing image enhanced endoscopy adjunct to white light imaging (WLI). As with the EPX-4440HD predicate device, the subject processor receives an image from the endoscope via a connector cable. The subject processor is capable of bi-directional communication that allows importation and exportation of various patient and procedural data between EMR (Electronic Medical Record) systems.

BLI and LCI are image processing features that a licensed medical practitioner (user) can utilize, as adjunctive tools, to supplement the white light endoscopic examination. The BLI and LCI features of VP-7000 and BL-7000 use narrow band short wavelength LED lights for outputting the spectrum image. BLI mode produces higher-contrast images of micro vessels by increasing the intensity ratio of the Violet LED light relatively as compared with WLI mode. BLI-bright mode can create brighter images than BLI, by slightly decreasing the intensity ratio of the Violet LED light relatively as compared with WLI mode. LCI mode produces enhanced mucous color by signal processing and increases the ratio of the Violet LED light relatively as compared with WLI mode.

The technological characteristics of BL-7000 are substantially equivalent to the predicate EPX-4440HD light source, except that it uses LED lights (like the CV-170) rather than Xenon lights.

Performance Data

Non-clinical testing:

VP-7000 and BL-7000 have no potential for patient contact. Therefore, biocompatibility testing for the subject device is not applicable.

Testing of the VP-7000 consisted of software validation in accordance with IEC 62304 and electrical safety in accordance with IEC 60601 requirements. Functional testing of the FICE, BLI, BLI-bright and LCI image processing features included Contrast Enhancement (or Color and Contrast Enhancement), Resolving Power, Noise, Artifact Creation, and Color Reproduction. All testing criteria were met, and in all instances the device functioned as intended.

Clinical testing:

The BLI and BLI-bright features were evaluated in a prospective clinical trial to objectively assess the overall image quality of each of the BLI and BLI-bright presets in comparison to the FICE presets (K140149). The study design was a reader concurrence study designed in accordance with the FDA document “Guidance on Solid State X-ray Imaging Devices” and consisted of two parts: (1) acquisition of images; and (2) reader study. Each subject (patient) underwent an endoscopic examination using VP-7000 Video Processor, BL-7000 Light Source and FUJIFILM’s video endoscopes during a single clinical procedure, first with white light imaging (WLI), followed by an

examination with FICE, BLI and BLI-bright imaging. The images were taken from different anatomic locations within the gastrointestinal tract (i.e., colon, duodenum, esophagus, or gastric region), and analyzed independently by multiple blinded investigators using a 4-point Likert scale. The clinical study established that BLI and BLI-bright demonstrated substantial equivalence of diagnostic visualization (e.g. image quality) to the predicate FICE.

Conclusions

FUJIFILM Processor VP-7000 and Light Source BL-7000 are substantially equivalent to their predicate devices, the EXP-4440HD Digital Video Processor with FICE and Light Source system (K140149) and the Olympus Video System Center CV-170 (K122831). VP-7000 and BL-7000 have the same intended use and similar indications, technological characteristics, and principles of operation as their predicate devices. The minor technological differences between VP-7000 and BL-7000 and their predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that Processor VP-7000 and Light Source BL-7000 are as safe and effective as the EXP-4440HD Digital Video Processor with FICE and Light source.

Thus, VP-7000 and BL-7000 are substantially equivalent to their predicate devices.

Comparison between the Subject Device and Predicate Devices

Device	Parameters	Primary Predicate: Fujifilm EPX-4440HD Digital Video Processor with FICE and Light Source	Secondary Predicate: OLYMPUS CV-170 VIDEO CENTER	Subject Device: FUJIFILM processor VP-7000 and Light source BL-7000
510(k) number		K140149	K122831	K163675
Indications for Use		The VP-4440 HD 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	This video system center is intended to be used with OLYMPUS video converter, camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.	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

Device	Parameters	Primary Predicate: Fujifilm EPX-4440HD Digital Video Processor with FICE and Light Source	Secondary Predicate: OLYMPUS CV-170 VIDEO CENTER	Subject Device: FUJIFILM processor VP-7000 and Light source BL-7000
		endoscope, light source, monitor, recorder and various peripheral devices. FICE is an adjunctive tool which can be used to supplement FUJIFILM white light endoscopy. FICE is not intended to replace histopathological sampling as a means of diagnosis.		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. Light Source BL-7000 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

Device	Parameters	Primary Predicate: Fujifilm EPX-4440HD Digital Video Processor with FICE and Light Source	Secondary Predicate: OLYMPUS CV-170 VIDEO CENTER	Subject Device: FUJIFILM processor VP-7000 and Light source BL-7000
				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.
Processor		VP-4440HD	CV-170	VP-7000
	Power Rating	120V AC 60Hz 0.8A	100-240V AC 50/60Hz 200VA	100-240V AC 50/60Hz 0.8-0.5A
	Compatible Endoscope	400 System Scope 500 System Scope 600 System Scope	100/130/140/150/160/180 Series and GI/BF/VISER A Series scope	500 System Scope 600 System Scope 700* System Scope (not available in USA)
	Keyboard	DK-4440E	MAJ-1981	DK-7000E
	Bi-Direction communication	Available	Unknown	Available
	Peripheral	Printer	Printer	Printer
	Digital Output	HD-SDI:HDTV 1080i DVI(Digital Visual Interface) Ethernet	HD-SDI SD-SDI DVI(Digital Visual Interface)	HD-SDI:HDTV 1080i DVI(Digital Visual Interface) Ethernet
	Analog Output	RGB, Y/C, Composite	RGB, Y/C, Composite, Y/PbPr, VBS	RGB, Y/C, Composite
	Analog Input	Not available	Not available	Composite
	Color Adjustment	Black, Red, Green, Blue, R-Hue, Chroma; 9steps	Red, Blue, Chroma; ±8steps	Black, Red, Green, Blue, R-Hue, Chroma; 9steps
	Enhancement	Hyper-Sharpness (Structure enhance) Color Enhance		Hyper-Sharpness (Structure enhance) Color Enhance
	FICE	Available	Not available	Available
	BLI	Not available	Not available	Available with E-600HL, EC-600LS, EG-600WR

Device	Parameters	Primary Predicate: Fujifilm EPX-4440HD Digital Video Processor with FICE and Light Source	Secondary Predicate: OLYMPUS CV-170 VIDEO CENTER	Subject Device: FUJIFILM processor VP-7000 and Light source BL-7000
				v2, and EC-600WL v2 and 700* series endoscopes
	BLI-bright	Not available	Not available	Available with E-600HL, EC-600LS, EG-600WR v2, and EC-600WL v2 and 700* series endoscopes
	LCI	Not available	Not available	Available with E-600HL, EC-600LS, EG-600WR v2, and EC-600WL v2 and 700* series endoscopes
	Iris	Average/Peak/Auto	Average/Peak/Auto	Average/Peak/Auto
	Peak Detection level	Available	Unknown	Available
	Shutter Speed	1/800 Max	Unknown	1/800 Max
	Shutter Speed Priority Mode	Available	Unknown	Available
	Default Pump Level Selection	Off/L/M/H	High, Low, Off	Off/L/M/H
	Mask Type	Type1/Type2	Unknown	Type1/Type2
	Image Storage	External Device and CF Card (Max16GB)	MAJ-1925 Olympus 2GB USB Portable Memory	External USB Memory (Max 2GB) and Internal Storage Memory
	Dimensions WxHxD mm	390x105x460 mm	295x145x425 mm	390x110x485 mm
	Weight	9.5kg	11kg	9kg
Light Source		XL-4450	CV-170	BL-7000
	Power Rating	120V AC 60Hz 3.3A	100-240V AC 50/60Hz 200VA	100-240V AC 50/60Hz 1.2-0.7A
	Lamp (power consumption)	Main Lamp: Xenon lamp (300W) Emergency lamp: Halogen lamp (75W)	LED lamp	Main Lamp: 4 LED Lamps (79.2W) Emergency lamp: when any LED lamp malfunctions (53.3W)
	Light Control	Peak/Average/Auto	Peak/Average/Auto	Peak/Average/Auto
	Air supply	Normal, Mid, Low,	High, Low, Off	Normal, Mid, Low, Off

Device	Parameters	Primary Predicate: Fujifilm EPX-4440HD Digital Video Processor with FICE and Light Source	Secondary Predicate: OLYMPUS CV-170 VIDEO CENTER	Subject Device: FUJIFILM processor VP-7000 and Light source BL-7000
	pump	Off		
	Dimensions WxHxD mm	390x155x450 mm	295x145x425 mm	390x155x485 mm
	Weight	15kg	11kg	12kg
Keyboard		DK-4440E	MAJ-1981	DK-7000E
		Basic US101 Keyboard Print for several keys are changed for the operation of VP-4440HD with FICE	Olympus Keyboard	Basic US101 Keyboard Print for several keys are changed for the operation of VP-7000

*Not Available In USA