



Food and Drug Administration
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March 3, 2016

Fujifilm Medical System USA, Inc.
Shraddha More
Specialist, Regulatory Affairs and Quality Assurance
10 High Point Drive
Wayne, NJ 07470

Re: K153206
Trade/Device Name: Fujifilm Ultrasonic Processors SU-1 PLATINUM and SU-1
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Codes: FDS, IYN, IYO, ITX
Dated: January 27, 2016
Received: January 28, 2016

Dear Shraddha 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 yours,


Herbert P. Lerner -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

Indications for Use

510(k) Number (if known)

K153206

Device Name

Fujifilm Ultrasonic Processors SU-1 PLATINUM and SU-1

Indications for Use (Describe)

The Fujifilm ultrasonic processors SU-1 PLATINUM and SU-1 are intended to be used in combination with Fujifilm ultrasonic endoscope, video processor, light source, monitor, recorder, and various peripheral devices. The product is intended to provide ultrasonic images of the trachea, bronchial tree and surrounding organs, or submucosal and peripheral organs of the upper gastrointestinal tract for observation, recording and to aid in diagnosis during endoscopic evaluation.

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 Medical Systems U.S.A., Inc.'s SU-1 and SU-1 PLATINUM

Submitter's Information:

Fujifilm Medical Systems U.S.A., Inc., Endoscopy Division
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FDA Establishment Registration Number: 2431293

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Date Prepared: November 4, 2015

Identification of the Proposed Device:

Proprietary/Trade Name: Fujifilm Ultrasonic Processor, Model SU-1 PLATINUM and SU-1
Common Name: Ultrasonic Processor

Device Class: Class II

Classification Information:

Classification Name	CFR Section	Product Codes
Gastroscope and accessories, flexible/rigid	21 CFR 876.1500	FDS
Ultrasonic Doppler Imaging System	21 CFR 892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	21 CFR 892.1560	IYO
Diagnostic Ultrasonic Transducer	21 CFR 892.1570	ITX

Predicate Devices

Fujinon Ultrasonic Processor SU-8000 (K111243)

Intended Use / Indications for Use

The Fujifilm ultrasonic processors SU-1 PLATINUM and SU-1 are intended to be used in combination with Fujifilm ultrasonic endoscope, video processor, light source, monitor, recorder, and various peripheral devices. The product is intended to provide ultrasonic images of the trachea, bronchial tree and surrounding organs, or submucosal and peripheral organs of the upper gastrointestinal tract for observation, recording and to aid in diagnosis during endoscopic evaluation.

Device Description

The Fujifilm ultrasonic processors SU-1 PLATINUM and SU-1 are used with previously cleared ultrasonic endoscopes, EG-530UR2 & EG-530UT2 (K120446) and EB-530US (K121035) to provide ultrasonic images of the trachea, bronchial tree, and surrounding organs, or submucosal and peripheral organs of the upper gastrointestinal tract for observation, recording and to aid in diagnosis during endoscopic evaluation.

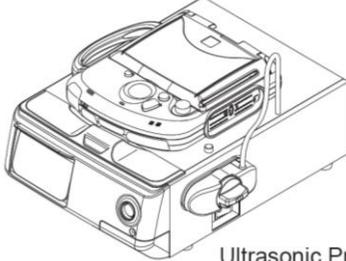
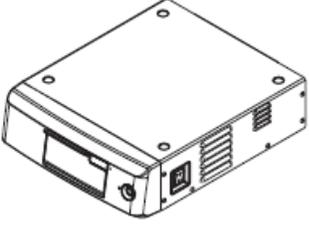
The Fujifilm ultrasonic processors SU-1 PLATINUM and SU-1 consist of two components, Processor and Keyboard, which are used in conjunction with one another. The SU-1 PLATINUM or SU-1 ultrasonic processors connect to an ultrasonic endoscope and transmit ultrasound waves into the body cavity by driving the transducer installed on the ultrasonic endoscope. The SU-1 PLATINUM or SU-1 ultrasonic processors process the reflected ultrasound signals received by the ultrasonic transducer in the body cavity and convert the electrical signals into image or video signals. The signals are displayed on the monitor or printer as ultrasonic images. The Keyboard, CP-1, is used to control operational features of the SU-1 PLATINUM or SU-1 ultrasonic processor.

The Fujifilm ultrasonic processor SU-1 PLATINUM and SU-1 can acquire and display real-time ultrasound data in different modes such as M, B, Color Doppler, Pulse Doppler, Duplex and Triplex. Additionally, SU-1 PLATINUM offers a feature/mode known as Elastography, which is a medical imaging modality that maps the elastic properties of the soft tissue of the target organs. Relative stiffness of the tissue is visualized as a color distribution map by a way of calculating the distortion of the tissue caused by external compression of inner vibration, and displaying disparities in stiffness levels as different colors.

Technological Characteristics

A comparison of the technological characteristics between the subject and predicate devices is provided in the table below.

	Fujinon Ultrasonic Processor SU-8000 (Predicate Device K111243)	Fujifilm Ultrasonic Processor SU-1/ SU-1 PLATINUM (Subject Device)
Intended Use/Indications for Use	The Fujinon ultrasonic processor SU-8000 is intended to be used in combination with Fujinon/Fujifilm ultrasonic endoscope, video processor, light source, monitor, recorder, and various peripheral devices. The product is intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, recording and to aid in diagnosis during endoscopic evaluation.	The FUJIFILM ultrasonic processors SU-1 PLATINUM and SU-1 are intended to be used in combination with FUJIFILM ultrasonic endoscope, video processor, light source, monitor, recorder, and various peripheral devices. The product is intended to provide ultrasonic images of the trachea, bronchial tree and surrounding organs, or submucosal and peripheral organs of the upper gastrointestinal tract for observation,

	Fujinon Ultrasonic Processor SU-8000 (Predicate Device K111243)	Fujifilm Ultrasonic Processor SU-1/ SU-1 PLATINUM (Subject Device)
		recording and to aid in diagnosis during endoscopic evaluation.
Appearance	 <p style="text-align: center;">Ultrasonic Processor SU-8000</p>	 <p style="text-align: center;">Ultrasonic Processor SU-1</p>
Compatible Endoscopes	EG-530UR/UR2 (Radial probe) EG-530UT/UT2 (Convex probe)	EG-530UR2 (Radial probe) EG-530UT2 (Convex probe) EB-530US (Convex probe)
Probe Type	Radial scan Convex scan	Same as the predicate device
Scanning Method	Electronic scan	Same as the predicate device
Image Mode	B-mode, M-mode, Color Doppler/Power Doppler, Pulsed Wave Doppler, THI Dual/Duplex/Triplex	B-mode, M-mode, Color Doppler/Power Doppler, Pulsed Wave Doppler, THI Dual/Duplex/Triplex Elastography (SU-1 PLATINUM only)
Frequency	5MHz/7.5MHz/10MHz/12MHz	Same as the predicate device
Display Range	EG-530UR/UR2: 15–120mm EG-530UT/UT2: 15–120mm Display depth:120mm (max)	EG-530UR2: 15mm–120mm EG-530UT2: 15mm–120mm EB-530US: 15mm–120mm Display depth:120mm (max)
Data Format	Data can be saved in JPEG format TIFF format DICOM format	Same as the predicate device
Measuring functions	Depth Distance Circumference Length/Area Volume Flow Velocity Acceleration A/B Ratio	Same as the predicate device
Compliance with Medical Electrical Safety and Performance Standard	IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-2-18, IEC60601-2-37	ANSI/AAMI ES60601-1, IEC60601-1-2, IEC60601-2-18, IEC60601-2-37

	Fujinon Ultrasonic Processor SU-8000 (Predicate Device K111243)	Fujifilm Ultrasonic Processor SU-1/ SU-1 PLATINUM (Subject Device)
Attenuation Spatial Peak Temporal Average Intensity (Ispta.3)	$I_{spta.3} \leq 720 \text{mW/cm}^2$	Same as the predicate device
Mechanical Index (MI)	1.9 or less	Same as the predicate device
Thermal Index (TI)	1.0 or less	Same as the predicate device
Dimensions (mm)	375(W) x 445(D) x 215(H)	390(W) x 485(D) x 135(H)
Weight	14Kg	13Kg
Control	Using Keyboard CP-8000	Using Keyboard CP-1
Power Requirements	AC120V	AC100-240V
Other equipment which can be used with the device	Video Processor Light Source Cart Monitor Recorder Color or Black & White Printer Foot Switch	Same as the predicate device

Performance Data

Fujifilm Ultrasonic Processors SU-1 PLATINUM and SU-1 are non-sterile and has no potential for patient contact. Testing of the SU-1 PLATINUM and SU-1 consisted of software validation in accordance with IEC 62304. Additionally, the devices were tested for EMC safety and performance in accordance to the requirements of the following standards and applicable quality system regulations: All predetermined testing criteria were met, and the device functioned as intended in all instances.

Standards No.	Standards Organization	Standards Title	Date
ES60601-1	ANSI/AAMI	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2010
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility Requirements and tests	2007
60601-1-6	IEC	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	2010
60601-2-18	IEC	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	2009
60601-2-37	IEC	Medical electrical equipment - part 2-37: particular requirements for the basic safety and essential performance of ultrasonic	2007

Standards No.	Standards Organization	Standards Title	Date
		medical diagnostic and monitoring equipment.	
62304	IEC	Medical device software - Software life-cycle processes	2006
62366	IEC	Medical devices -Application of usability engineering to medical devices	2007
62359	IEC	Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields	2005
UD2	NEMA	Acoustic output measurement standard for diagnostic ultrasound equipment	2004

Substantial Equivalence

Fujifilm Ultrasonic Processors SU-1 PLATINUM and SU-1 is comparable with and substantially equivalent to the predicate, Fujinon Ultrasonic Processor SU-8000. The SU-1 PLATINUM and SU-1 has the same intended use, and substantially similar indications for use, technological characteristics, and principles of operation as their predicate device SU-8000. The key differences between the SU-1 PLATINUM and SU-1 and their predicate device are expanded indications for use and the addition of the elastography function in the SU-1 Platinum.

The indications for use have been expanded to include additional clinical applications such as the trachea, bronchial tree, and surrounding organs to accommodate the use of the SU-1 and SU-1 Platinum with Fujifilm's currently marketed ultrasonic bronchoscope EB-530US (K121035) which is cleared for these same clinical applications. Additionally, the SU-1 PLATINUM offers a feature, known as elastography imaging, which is not present in the SU-8000 predicate, but is supported by a substantially similar elastography imaging feature in the Olympus EU-Y0008 (also known as EU-ME2 premier plus) (K130058) which is cited as a reference device.

These differences in indications for use and technology of the SU-1 PLATINUM and SU-1 and their predicate device SU-8000 do not raise new concerns regarding safety or effectiveness. Bench testing data demonstrated that the subject ultrasonic processors have substantially equivalent performance and safety to their predicate.

Conclusions

The SU-1 PLATINUM and SU-1 are substantially equivalent to the similar legally marketed device SU-8000, and conform to applicable medical device safety and performance standards.