January 11, 2018

FUJIFILM Medical Systems U.S.A., Inc.
Jeffrey Wan
Specialist, Regulatory Affairs
10 High Point Drive
Wayne, NJ 07470

Re: K171207
Trade/Device Name: FUJIFILM Ultrasonic Processor SP-900 and Ultrasonic Probe PB2020-M
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODG, IYO, ITX
Dated: November 30, 2017
Received: December 1, 2017

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 *See PRA Statement on last page*

510(k) Number *(if known)*

K171207

Device Name

FUJIFILM Ultrasonic Processor SP-900 and Ultrasonic Probe PB2020-M

Indications for Use *(Describe)*

SP-900:

The FUJIFILM Ultrasonic Processor SP-900 is intended to be used in combination with FUJIFILM Ultrasonic Probe, video processor, light source, monitor, recorder, and various peripheral devices. The product is intended to provide ultrasonic images of the gastrointestinal tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree for observation, recording and to aid in diagnosis during endoscopic evaluation.

PB2020-M:

This product is a medical ultrasonic probe. It is intended for the observation and diagnosis of the gastrointestinal tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree under the management of physicians at medical facilities.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

FUJIFILM Medical Systems, U.S.A., Inc.'s

FUJIFILM Ultrasonic Processor SP-900 and Ultrasonic Probe PB2020-M

Submitter's Information:

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

Contact Person:

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Date Prepared: January 9, 2018

Identification of the Proposed Device:

Trade/Device Name:	FUJIFILM Ultrasonic Processor SP-900, FUJIFILM Ultrasonic Probe PB2020-M
Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscope and Accessories
Regulation Class:	Class II
Product Codes:	ODG, IYO, ITX

Predicate Device:

Endoscopic Ultrasound Center EU-Y0008 (marketed as EU-ME2), Olympus Medical Systems Corp., K130058

Intended Use / Indications for Use:

SP-900:

The FUJIFILM Ultrasonic Processor SP-900 is intended to be used in combination with FUJIFILM Ultrasonic Probe, video processor, light source, monitor, recorder, and various peripheral devices. The product is intended to provide ultrasonic images of the gastrointestinal tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree for observation, recording and to aid in diagnosis during endoscopic evaluation.

PB2020-M:

This product is a medical ultrasonic probe. It is intended for the observation and diagnosis of the gastrointestinal tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree under the management of physicians at medical facilities.

Device Description:

The FUJIFILM Ultrasonic Processor SP-900 and Ultrasonic Probe PB2020-M consists of five components: 1) processor (SP-900), 2) probe (PB2020-M), 3) control pad (CP-900), 4) scanner (RS-900), and 5) power cord. The SP-900 generates ultrasound waves into the body cavity by driving the ultrasonic transducer installed in the PB2020-M, which is inserted through the forceps channel of an endoscope. The SP-900 processes the reflected ultrasound signals which the PB2020-M receives in the body cavity and further converts the processed electrical signals into video signals to relay to a monitoring system. The SP-900 can acquire and display real-time ultrasound data in B-mode. The CP-900 is used to control operational features of the SP-900. The RS-900 provides the mechanical scanning for acquiring a two-dimensional image. The power cord supplies power to the SP-900.

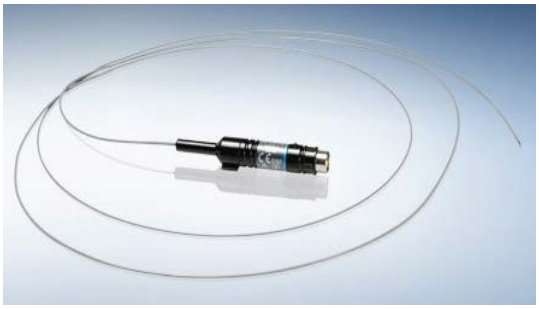
Technological Characteristics:

A comparison of the technological characteristics between the subject and predicate device is provided in the table below. The predicate device is specified as the EU-ME2 connected to UM-S20-17S ultrasonic probe.

	Proposed Device	**Predicate Device**
Device name	SP-900	EU-ME2
Common name	Ultrasonic processor	Ultrasonic processor
Manufacturer	FUJIFILM Medical Systems U.S.A., Inc.	Olympus Medical Systems Corp.
510(k) number	To be assigned	K130058
Intended Use/Indications for Use	The FUJIFILM Ultrasonic Processor SP-900 is intended to be used in combination with FUJIFILM Ultrasonic Probe, video processor, light source, monitor, recorder, and various peripheral devices. The product is intended to provide ultrasonic images of the gastrointestinal tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree for observation, recording and to aid in diagnosis during endoscopic evaluation.	This ultrasound center is intended to be used with Olympus ultrasound endoscopes, Olympus ultrasound probes or Olympus esophageal ultrasound probes to observe and to store real-time ultrasound images and indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree, and urinary tract.
Appearance		
Compatible transducer	PB2020-M	UM-S20-17S
Probe type	Radial scan	Radial scan

Scanning method	Mechanical scan	Mechanical scan
Image mode	B-mode	B-mode
Frequency	20MHz	20MHz
Display range	20mm, 30mm, 40mm, 60mm, 90mm, 120mm diameter	20mm, 30mm, 40mm, 60mm, 90mm, 120mm diameter
Data format	JPEG, TIFF	JPEG, BMP
Measuring functions	Distance Circumference Length/Area	Distance Circumference Length/Area
Compliance with Medical Electrical Safety and Performance Standard	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-2-37	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-2-37
Attenuation Spatial Peak Temporal Average Intensity	$I_{SPTA.3} \leqq 720 mW/cm^2$	$I_{SPTA.3} \leqq 720 mW/cm$
Mechanical Index (MI)	Less than 1.0	Less than 1.0
Thermal Index (TI)	Less than 1.0	Less than 1.0
Dimensions (mm)	377(W) x 480(D) x 80(H)	371(W) x 480(D) x 175(H)
Weight (kg)	8.0	22.5
Control	CP-900	MAJ-1995
Mechanical drive	RS-900	MAJ-935
Power requirements	AC100-240V	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 USB Memory Ultrasonic Processor	Video Processor Light Source Cart Monitor Recorder Color or Black & White Printer Foot Switch USB Memory

	Proposed Device	**Predicate Device**
Device name	PB2020-M	UM-S20-17S
Common name	Ultrasonic probe	Ultrasonic probe
Manufacturer	FUJIFILM Medical Systems U.S.A., Inc.	Olympus Medical Systems Corp.
510(k) number	To be assigned	K130058

Intended Use/Indications for Use	This product is a medical ultrasonic probe. It is intended for the observation and diagnosis of the gastrointestinal tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree under the management of physicians at medical facilities.	UM-S20-17S is designed for use with in combination with Olympus endoscopic ultrasound system for intraluminal sonographic imaging of gastrointestinal tract wall; biliary (common bile, cystic, intrahepatic); pancreatic ducts; surrounding organs and upper airways and tracheobronchial tree.
Appearance		
Diameter of insertion portion	1.4-1.9mm	1.4-1.7mm
Maximum diameter of insertion portion	2.0mm	1.8mm
Working length	2150mm	2150mm
EOG Sterilization	Applicable	Applicable
Applicable system	FUJIFILM SP-900	Olympus EU-ME2
Applicable scope	Endoscopes that meet the following conditions: Channel diameter ≥ 2.0mm Working length ≤ 1330mm Endoscope types: − Bronchoscope − Upper gastrointestinal endoscope − Large intestine endoscope − Duodenoscope	Olympus flexible endoscopes without guide sheath that meet the following conditions: Channel diameter ≥ 2.0mm Working length ≤ 1330mm Endoscope types: − Bronchoscope − Gastroscope − Colonoscope − Duodenoscope − Choledochoscope
Scanning method	Mechanical radial	Mechanical radial
Ultrasonic frequency	20MHz	20MHz

Performance Data:

FUJIFILM Ultrasonic Processor SP-900 is non-sterile and has no potential for patient contact. Testing of the SP-900 consisted of software validation in accordance with IEC 62304.

Ultrasonic Probe PB2020-M was tested for biocompatibility according to ISO 10993. Cleaning, disinfection, and sterilization were also evaluated.

Testing was conducted on the SP-900 in combination with PB2020-M to ensure that the image quality and performance met all internally established specifications.

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	2012
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	2013
60601-2-37	IEC	Medical electrical equipment – Part 2-37: particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	2007
62304	IEC	Medical device software – Software life-cycle processes	2006
62359	IEC	Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasound fields	2010
62366	IEC	Medical devices – Application of usability engineering to medical devices	2014
10993-5	ISO	Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity.	2009
10993-10	ISO	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.	2010
14971	ISO	Medical devices – Application of risk management to medical devices	2007
UD2	NEMA	Acoustic output measurement standard for diagnostic ultrasound equipment	2009

Substantial Equivalence:

FUJIFILM Ultrasonic Processor SP-900 is comparable with and substantially equivalent to the predicate, Endoscopic Ultrasound Center EU-Y0008 (K130058), which is marketed as the EU-ME2.

The proposed device has the same general intended use and similar indications, technological characteristics, and principles of operation as the predicate device. The key difference between the proposed and predicate devices is the expanded indications in the predicate device that are not found in the subject device.

The SP-900 is intended for use with the Ultrasonic Probe PB2020-M, which is not intended for use with the EU-ME2. However, the PB2020-M is substantially equivalent to the UM-S20-17S, which is intended for use with the EU-ME2. The PB2020-M has the same general intended use and similar indications, technological characteristics, and principles of operation as the UM-S20-17S.

The differences in indications and technological characteristics between the subject and predicate devices do not raise new concerns regarding safety and effectiveness. Bench testing data demonstrates that the SP-900 with PB2020-M is substantially equivalent to the EU-ME2 with UM-S20-17S in safety and effectiveness.

Conclusions:

The SP-900 and PB2020-M are substantially equivalent to the similar legally marketed devices EU-ME2 and UM-S20-17S and conforms to applicable medical device safety and performance standards.