June 3, 2022

Fujifilm Corporation
% Kotei Aoki
Senior Regulatory Affairs Specialist
Fujifilm Healthcare Americas Corporation
81 Hartwell Avenue, Suite 300
LEXINGTON MA 02421

Re: K214089
Trade/Device Name: FUJIFILM Ultrasonic Processor SP-900 and FUJIFILM Ultrasonic Probe PB2020-M2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: ODG, IYO, ITX
Dated: May 2, 2022
Received: May 3, 2022

Dear Kotei Aoki:

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,

For

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT 8: Office of Radiological Health
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)*
K214089

Device Name
FUJIFILM Ultrasonic Processor SP-900 and FUJIFILM Ultrasonic Probe PB2020-M2

Indications for Use *(Describe)*

FUJIFILM Ultrasonic Processor 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.

Modes of Operation: B-mode

FUJIFILM Ultrasonic Probe PB2020-M2

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.

Modes of Operation: B-mode

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 - K214089

FUJIFILM Corporation

FUJIFILM Ultrasonic Processor SP-900 and FUJIFILM Ultrasonic Probe PB2020-M2

Date: December 27, 2021

Submitter's Information:
FUJIFILM Corporation
798 MIYANODAI KAISEI-MACHI
ASHIGARAKAMI-GUN, KANAGAWA
258-8538 JAPAN

Contact Person:
Kotei Aoki
Senior Regulatory Affairs Specialist
E-Mail: Kotei.Aoki@fujifilm.com
Telephone: (765) 246- 2931

Identification of the Subject Device:

Device Name	FUJIFILM Ultrasonic Processor SP-900	FUJIFILM Ultrasonic Probe PB2020-M2
Common Name	Ultrasonic Processor	Ultrasonic Probe
Product Code	• ODG • IYO	• ITX
Device Class	Class 2	Class 2
Regulation Number	• 876.1500 • 892.1560	• 892.1570
Regulation Description	• Endoscopic Ultrasound System, Gastroenterology-Urology; • System, Imaging, Pulsed Echo, Ultrasonic	• Transducer, Ultrasonic, Diagnostic
Review Panel	• Gastroenterology/Urology • Radiology	• Radiology

Predicate Device(s):

- FUJIFILM Ultrasonic Processor SP-900 and FUJIFILM Ultrasonic Probe PB2020-M (K171207)

Intended Use / Indications for Use:
FUJIFILM Ultrasonic Processor 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.
Modes of Operation: B-mode

FUJIFILM Ultrasonic Probe PB2020-M2

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.
Modes of Operation: B-mode

Device Description:

The FUJIFILM Ultrasonic Processor SP-900 and FUJIFILM Ultrasonic Probe PB2020-M2 consists of five components: 1) processor (SP-900), 2) probe (PB2020-M2), 3) control pad (CP-900), 4) scanner (RS-900), and 5) power cord. SP-900 generates ultrasound waves into the body cavity by driving the ultrasonic transducer installed in PB2020-M2, which is inserted through the forceps channel of an endoscope. SP-900 processes the reflected ultrasound signals which PB2020-M2 receives in the body cavity and further converts the processed electrical signals into video signals to relay to a monitoring system. SP-900 can acquire and display real-time ultrasound data in B-mode. CP-900 is used to control operational features of SP-900. RS-900 provides the mechanical scanning for acquiring a two-dimensional image. The power cord supplies power to SP-900.

Comparison of Technological Characteristics:

Comparisons of technological characteristics between the subject devices and the predicate devices are provided in the tables below:

Table 1

	Subject device model SP-900	**Predicate device model SP-900**	**Remark**
Device name	Ultrasonic processor	Ultrasonic processor	
510(k) number	K214089	K171207	
Indications for use (IFU)	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. Modes of Operation: B-mode		Same
Compatible transducer	PB2020-M2, PB2020-M	PB2020-M	
Physical specification			
Size (mm)	377(W) x 480(D) x 80(H)		Same
Weight (kg)	8.0		Same
Power requirements (V)	AC 100-240		Same
Scan specification			
Probe type	Radial scan		Same
Scanning method	Mechanical scan		Same
Image mode	B-mode		Same
Frequency (Mhz)	20		Same
Measuring functions	Distance; Circumference Length/Area		Same
Output specification			
Display range (mm)	20, 30, 40, 60, 90, 120 in diameter		Same
Data format	JPEG, TIFF		Same
Electrical Safety			
Spatial Peak Temporal Average Intensity	≤ 720 mW/cm^2		Same
Mechanical Index	< 1.0		Same
Thermal Index	< 1.0		Same
Compatible Peripherals			
Control	CP-900		Same
Mechanical drive	RS-900		Same
Other compatible peripherals	Video Processor, Light Source, Cart, Monitor, Recorder, Printer, Foot Switch, USB Memory		Same

Table 2

	Subject device model PB2020-M2	**Predicate device model PB2020-M**	**Remark**
Device name	Ultrasonic probe	Ultrasonic probe	
510(k) number	K214089	K171207	
Indications for use (IFU)	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. Modes of Operation: B-mode		Same
Probe specification			
Diameter of insertion portion (mm)	1.4～1.9		Same
Working length (mm)	2150		Same
Maximum outer diameter of insertion portion (mm)	1.98	2.0	
Reprocessing method			
Manual cleaning	Applicable		Same
High-Level Disinfection	Applicable		Same
EOG Sterilization	Applicable		Same
STERRAD Sterilization	Applicable	Not applicable	
Compatibility			
Applicable system	SP-900		Same
Applicable scope	FUJIFILM endoscopes that meet the following conditions • Channel diameter: ≥2.0mm • Working length: ≤1330mm • Any of the following types of endoscope ○ Bronchoscope ○ Upper gastrointestinal endoscope ○ Lower gastrointestinal endoscope ○ Duodenoscope	FUJIFILM endoscopes that meet the following conditions • Channel diameter: ≥2.0mm • Working length: ≤1330mm • Any of the following types of endoscope ○ Bronchoscope ○ Upper gastrointestinal endoscope ○ Large intestine endoscope ○ Duodenoscope	Same
Ultrasound specification			
Scanning method	Mechanical radial		Same
Acoustic operating frequency (Mhz)	20		Same
Resolution (mm)	Axial: ≤ 2.0 Lateral: ≤ 2.0		Same
Penetration depth (mm)	7.0		Same

Performance Data:

FUJIFILM Ultrasonic Processor SP-900 is supplied non-sterile but has no potential for patient contact. FUJIFILM Ultrasonic Probe PB2020-M2 is also supplied non-sterile and must be properly reprocessed prior to each use in accordance with its reprocessing instructions. The cleaning, disinfection, and sterilization were validated on PB2020-M2. The STERRAD sterilization validation was also conducted.

The biocompatibility was evaluated 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'", issued September 4, 2020. The cytotoxicity was evaluated according to ISO 10993-5. The sensitization and irritation testing were conducted according to ISO 10993-10.

The subject devices SP-900 and PB2020-M2 contain electronic components. The subject device SP-900 has the same electrical components and can be adopted into electrical safety of the predicate device SP-900. Meanwhile, the software validation for the SP-900 was conducted in accordance with IEC 62304. The testing was conducted to ensure the electrical safety of the subject device PB2020-M2 according to ANSI/AAMI ES60601-1 and IEC 60601-2-37:2007. The subject devices SP-900 and PB2020-M2 were evaluated for the electromagnetic compatibility according to IEC 60601-1-2:2014.

Conclusions:

The subject device FUJIFILM Ultrasonic Processor SP-900 is intended to be used with the FUJIFILM Ultrasonic Probe PB2020-M2. The subject devices share the same intended use and indications, technological characteristics, principles of operation, and reprocessing methods as the respective predicate devices. The key differences are the modification to the materials of construction in PB2020-M2 and the addition of STERRAD sterilization method for reprocessing PB2020-M2. The validation and test results demonstrate that the key differences between the subject devices and the predicate devices do not raise new concerns regarding safety and effectiveness.

The subject devices FUJIFILM Ultrasonic Processor SP-900 and FUJIFILM Ultrasonic Probe PB2020-M2 are substantially equivalent to the respective predicate devices FUJIFILM Ultrasonic Processor SP-900 and FUJIFILM Ultrasonic Processor PB2020-M (K171207).