Fujifilm Healthcare Americas Corporation
℅ Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
798 MIYANODAI KAISEI-MACHI
ASHIGARAKAMI-GUN, KANAGAWA 258-8538
JAPAN

December 13, 2023

Re: K231666
Trade/Device Name: Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: ITX
Dated: November 7, 2023
Received: November 7, 2023

Dear Chaitrali Kulkarni:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: 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.

Submission Number *(if known)*

K231666

Device Name

Endoscopic Ultrasonic Probe (P2612S-L);
Endoscopic Ultrasonic Probe (P2620S-L)

Indications for Use *(Describe)*

This product is a medical ultrasonic probe. It is intended for the observation and diagnosis of the gastrointestinal tract and surrounding organs under the management of physicians at medical facilities. This product is intended for adults.
Modes of Operation: B-mode
Never use this product for any other purposes.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K231666

FUJIFILM Corporation

FUJIFILM Ultrasonic Probe P2612S-L/P2620S-L

Date: December 13, 2023

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

Contact Person:
Chaitrali Kulkarni
Senior Regulatory Affairs Specialist
E-Mail:
chaitrali.kulkarni@fujifilm.com
Telephone: (704) 517 4886

Identification of the Subject Device:

Device Name	Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)
Common Name	Ultrasonic Probe
Product Code	• ITX
Device Class	Class 2
Regulation Number	• 892.1570
Regulation Description	• Diagnostic ultrasonic transducer
Review Panel	• Radiology

Predicate Device:

- OLYMPUS UM-S30-25R ULTRASONIC PROBE AND ASSOCIATED ANCILLARY EQUIPMENT FOR GASTROINTESTINAL TRACT (K994103)

Reference Device:

- Modifications to EUB-525 Diagnostic Ultrasound Scanner; EUB-2000 Diagnostic Ultrasound Scanner; Sp-711 Sonoprobe System (K012239)

Intended Use / Indications for Use:

This product is a medical ultrasonic probe. It is intended for the observation and diagnosis of the gastrointestinal tract and surrounding organs under the management of physicians at medical facilities. This product is intended for adults.
Modes of Operation: B-mode
Never use this product for any other purposes.

Device Description:

FUJIFILM Endoscopic Ultrasonic Probe converts the electrical signal from the ultrasonic observation device connected via the probe scanner into ultrasonic waves by the ultrasonic transducer placed at the tip of this product and emits it and receives reflected waves from the human body. The received wave is converted into an electric signal by transducer and sent to an ultrasonic diagnostic device to create an ultrasonic image. The scanning method is a mechanical radial method by using a probe scanner.

Based on the guidance, *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* (Feb. 2023), this device follows the **track 3** designation, as it does conform to IEC 60601-2- 37. The transducer model designation and type are a mechanical radial scan, with a size and spacing of elements of 1.9×2.0×0.6mm[W×L×T]. There is one element in the array, with array dimensions of one and the maximum number of active elements for a single pulse is one. The nominal ultrasonic frequency of the transducer assembly for the P2612S-L is 10MHz and for P2620S-L is 17MHz, both in combination with 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

Device name	Predicate Device Olympus Ultrasonic Probe	Reference Device:	Proposed Device Endoscopic Ultrasonic Probe	Equivalence
	UM-S30-25R	PL2226-12	P2612S-L/P2620S-L	
		P2226-20		
510(k) number	K994103	K012239	K231666	

Indications for use (IFU)	The Olympus UM-S30-25R Ultrasonic Probe has been designed to be used with an Olympus Endoscopic Ultrasound center, Probe Driving Unit and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract and surrounding organs. Modes of Operation: B-mode	The intended use of the subject device is for endoscopic observation of the gastrointestinal tract (esophagus, stomach, duodenum, large intestine) and biliary system (pancreato-biliary ducts). The Ultrasound Device Indications Statements for each application and mode of the system/transducers are included with this document.	This product is a medical ultrasonic probe. It is intended for the observation and diagnosis of the gastrointestinal tract and surrounding organs under the management of physicians at medical facilities. This product is intended for adults. Modes of Operation: B-mode Never use this product for any other purposes.	Same
Probe specification				
Diameter of insertion portion	2.4mm	2.6mm	2.5mm	The proposed device and the predicate device have different insertion portion diameters, however the proposed device has a smaller insertion portion diameter than the reference device, therefore there is no new concern for safety and efficacy.
Maximum diameter of insertion portion		2.7mm	2.6mm	The proposed device and the reference device have different maximum diameter of

					insertion portion, however the proposed device has a smaller insertion portion diameter than the reference device, therefore there is no new concern for safety and efficacy.
Working length		2050mm	2180mm	2620mm	Although the length of the proposed device is longer, the working length of the proposed device is compatible with the working length of its compatible endoscope, therefore there are no new concerns for the safety and efficacy of the proposed device.
Applicable reprocess method	Manual cleaning		Applicable	Applicable	Same as reference device
	Manual disinfection		Applicable	Applicable	Same as reference device
	Endoscope automatic cleaning and disinfection		Not Applicable	Applicable	The proposed device does have automatic cleaning and disinfection although the reference device does not. The difference in applicable reprocess methods does not affect the safety and efficacy of the device and cleaning instructions have been provided in the operation manual.
	EOG		Not Applicable	Applicable	EOG sterilization is

	Sterilization				applicable to the proposed device but not the reference device. The difference in applicable reprocess methods does not affect the safety and efficacy of the device and cleaning instructions have been provided in the operation manual.
	Stellad Sterilization		Not applicable	Not applicable	Same as reference device
Applicable system		Olympus Endoscopic Ultrasound center, Probe Driving Unit and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract and surrounding organs.	SP-711	SP-900	The difference in applicable systems between the subject device and predicate device do not affect the safety or efficacy of the subject device. The subject device has been tested with the SP-900 processor and the applicable system is listed in the operation manual.
Applicable scope		Flexible endoscope: inner channel is 2.8mm, 3.2mm,4.2mm,6mm and 5.Smm. Rigid endoscopes: minimum capacity is 9Fr.	Direct-viewing type endoscopes with a forceps channel diameter of 2.8 mm or more and a working length of 1700 mm or less	FUJIFILM endoscope -Upper gastrointestinal endoscope -Lower gastrointestinal endoscope *1 The instrument channel diameter of each endoscope must be 2.8 mm or more and its working length 2200 mm or less. *2 This product is not applied in combination	The differences in the applicable scope do not affect the safety or efficacy of the subject device. The subject device has been tested with its applicable scope and no new concerns for safety or efficacy was seen.

			with Duodenoscope and Ultrasonic endoscope.	
Ultrasound specification				
Scanning method	Mechanical radial	Mechanical radial	Mechanical radial	same
Sound operating frequency	30MHz	PL2226-12： 12MHz±20% PL2226-20： 18MHz±20%	P2612S-L： 10MHz±15% P2620S-L： 17MHz±15%	The differences in the ultrasound specification from the predicate device and the proposed device have been tested according to 60601-2-37
Resolution		Axial: 1.5mm or less Lateral: 3.0mm or less	Axial: 1.0mm or less Lateral: 3.0mm or less	The differences in the ultrasound specification from the predicate device and the reference device have been tested according to 60601-2-37.
Penetration		PL2226-12：15mm PL2226-20：5mm	P2612S-L：20mm P2620S-L: 5mm	The differences in the ultrasound specification from the predicate device and the proposed device have been tested according to 60601-2-

				37.
Patient contact materials				
Insertion portion		Distal end cap：Polyethylene ・Distal ring：Stainless steel rod ・Bonded part：Epoxy resin ・Sheath：Polytetrafluoroethylene	・Distal end cap：Polyethylene ・Distal ring：Stainless steel rod ・Bonded part：Epoxy resin ・Sheath：Polytetrafluoroethylene	Same as reference device

Performance Data:

FUJIFILM Ultrasonic P2612S-L/P2620S-L is 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 P2612S-L/P2620S-L.

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 2018. The cytotoxicity was evaluated according to ISO 10993-5. The sensitization study was conducted according to 10993-10 and irritation testing was conducted according to ISO 10993-23.

The subject device P2612S-L/P2620S-L contains electronic components. The testing was conducted to ensure the electrical safety of the subject device P2612S-L/P2620S-L according to ANSI/AAMI ES60601-1 and IEC 60601-2-37:2007. The subject device P2612S-L/P2620S-L along with the applicable system (SP-900) was evaluated for the electromagnetic compatibility according to IEC 60601-1-2:2014.

Clinical Testing:

Clinical testing is not applicable to this submission.

Conclusions:

The subject device FUJIFILM Ultrasonic Probe P2612S-L/P2620S-L and predicate device, Olympus UM-S30-25R Ultrasonic Probe and Associated Ancillary Equipment for Gastrointestinal Tract, have slight differences in the technological characteristics. Although there are differences in technological characteristics those differences do not raise any new concerns for safety and efficacy.

The subject device FUJIFILM Ultrasonic Probe P2612S-L/P2620S-L is substantially equivalent to the respective predicate device Olympus UM-S30-25R Ultrasonic Probe and Associated Ancillary Equipment for Gastrointestinal Tract (K994103)