July 6, 2020

FUJIFILM Corporation
% Kamila Sak
Regulatory Affairs Specialist
FUJIFILM Medical System U.S.A., Inc.
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K200850
Trade/Device Name: Fujifilm Ultrasonic Processor, Model SU-1 Platinum and SU-1
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS, IYN, IYO, ITX
Dated: June 15, 2020
Received: June 16, 2020

Dear Kamila Sak:

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
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200850

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
Fujifilm Ultrasonic Processor, Model SU-1 PLATINUM and SU-1

Date: June 15, 2020

Submitter's Information:

FUJIFILM Corporation
798 Miyanodai Kaisei-Machi
Ashigarakami-Gun, Kanagawa, 258-8538, Japan
FDA Establishment Registration Number: 3001722928

Contact Person:

Kamila Sak
Regulatory Affairs Specialist
Telephone: (347) 577-2309
E-Mail: kamila.sak@fujifilm.com
Regulatory Affairs Specialist

Identification of the Proposed Device:

Device Name:	Fujifilm Ultrasonic Processor, Model SU-1 PLATINUM and SU-1
Common Name:	Ultrasonic Processor
Classification Number:	21 C.F.R. § 876.1500
Classification Name:	Endoscope and accessories
Regulatory Class:	Class II
Device Panel:	Gastroenterology/Urology

Product Code Information:

Product Code Name	CFR Section	Product Codes
Gastroscope and accessories, flexible/rigid	21 CFR 876.1500	FDS (Primary Product Code)
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 Device:

Fujifilm Ultrasonic Processor, Model SU-1 PLATINUM and SU-1 (K153206)

Intended Use / Indications for Use:

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 (K181763), EB-530US (K182825), EG-580UR and EG-580UT (K183433).

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/CP-1TB, is used to control operational features of the SU-1 PLATINUM or SU-1 ultrasonic processor. Furthermore, the SU-1 PLATINUM and SU-1 system can be expanded by connecting additional devices. The system can optionally be used with a previously cleared FUJIFILM Ultrasonic Processor SP-900 (K171207).

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, F-Flow, Duplex and Triplex.

Additionally, SU-1 PLATINUM offers a feature/mode known as Elastrography, 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:

The proposed device SU-1 PLATINUM and SU-1 differs from the predicate device in the following minor modifications:

- Software version update to v1.17 to include view mode: F-Flow, which is a modification of power doppler mode
- Addition of two compatible endoscopes: EG-580UR (Radial probe) and EG-580UT (Convex probe) previously cleared in K183433

Performance Data:

Electrical safety of the proposed device was evaluated using the following standards: ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012, IEC 60601-1-6:2013, IEC 60601-1-2:2014, IEC 60601-2-37:2015, and IEC 60601-2-18:2009.

Software validation was evaluated in accordance with IEC 62304:2015 and the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," published May 11, 2005. Cybersecurity controls were developed according to the FDA guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," published October 2, 2014.

Fujifilm conducted Doppler sensitivity for F-Flow mode performance testing on the proposed device SU-1 PLATINUM and SU-1 to ensure that the modified device performs equivalently to the predicate device. The device met the pre-defined acceptance criteria for the test.

Substantial Equivalence:

The company's SU-1 PLATINUM and SU-1 has the same intended use and indications for use as the previously cleared predicate SU-1 PLATINUM and SU-1 (K153206). In addition, the proposed device has similar technological characteristics and principles of operation as the predicate. The minor differences between the proposed and predicate devices do not raise new or additional questions of safety or effectiveness of the proposed devices. Thus, the proposed device SU-1 PLATINUM and SU-1 is substantially equivalent to the predicate device.

Conclusions:

The modified SU-1 PLATINUM and SU-1 is substantially equivalent to the predicate and conforms to applicable medical device safety and performance standards.