



Food and Drug Administration
10903 New Hampshire Avenue
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FUJIFILM SonoSite, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

April 5, 2016

Re: K160734
Trade/Device Name: SonoSite SII Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: March 16, 2016
Received: March 17, 2016

Dear Mr. Job:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a large, faint, light-blue watermark of the FDA logo.

FOR

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

TBD K160734

Device Name

SonoSite SII Ultrasound System

Indications for Use (Describe)

The SonoSite SII Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

Ophthalmic

Fetal - OB/GYN

Abdominal

Pediatric

Small Organ (breast, thyroid, testicle, prostate)

Neonatal Cephalic

Adult Cephalic

Trans-vaginal

Musculo-skeletal (Conventional)

Musculo-skeletal (Superficial)

Cardiac Adult

Cardiac Pediatric

Peripheral Vessel

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

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

FUJIFILM SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

Corresponding Official: Patricia Liao
Manager, Regulatory Affairs
E-mail: Patricia.Liao@sonosite.com
Telephone: (425) 951-6870
Facsimile: (425) 951-1201
Date prepared: March 2, 2016

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories
Proprietary Name

SonoSite SII Ultrasound System (*subject to change*)

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Identification of the predicate or legally marketed device:

SonoSite Edge II Ultrasound System K153626
SonoSite S Series (Maxx Series) Ultrasound System K130173

4) Device Description:

The SonoSite SII Ultrasound System is a mountable style, full featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through multiple imaging modes. SII is a custom fabricated digital electronic design that readily lends itself to be configured for specific ultrasound imaging applications through different system feature selections. SII can operate on either battery or AC power.

5) Intended Use:

The FUJIFILM SonoSite SII Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

- Ophthalmic
- Fetal - OB/GYN
- Abdominal
- Pediatric
- Small Organ (breast, thyroid, testicle, prostate)
- Neonatal Cephalic
- Adult Cephalic
- Trans-vaginal
- Musculo-skeletal (Conventional)
- Musculo-skeletal (Superficial)
- Cardiac Adult
- Cardiac Pediatric
- Peripheral Vessel

6) Technological Characteristics:

SonoSite Edge II and S Series Ultrasound Systems are both Track 3 devices that employ the same fundamental scientific technology. A comparison table is provided below.

Feature	SonoSite SII Ultrasound System (This submission)	SonoSite Edge II Ultrasound System (K153626)	SonoSite S Series Ultrasound System (K130173)
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body
Indications for Use	Ophthalmic Fetal – OB/GYN Abdominal Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Peripheral Vessel Needle guidance	Ophthalmic Fetal – OB/GYN Abdominal Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel Needle guidance	Ophthalmic Fetal - OB/GYN Abdominal Intra-operative (Abdominal organs and vascular) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel Needle guidance
Transducer Types	Linear Array Curved Linear Array Intracavitary Phased Array	Linear Array Curved Linear Array Intracavitary Phased Array Trans-esophageal	Linear Array Curved Linear Array Intracavitary Phased Array Static Probes Trans-esophageal
Transducer Frequency	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz

Feature	SonoSite SII Ultrasound System (This submission)	SonoSite Edge II Ultrasound System (K153626)	SonoSite S Series Ultrasound System (K130173)
Modes of Operation	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Color M-Mode Color Power Doppler Zoom Combination Modes SonoHD2 Noise Reduction SonoMB/MBe Image Compounding Velocity Color Doppler	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Color M-Mode Color Power Doppler Zoom Combination Modes Pulsed Wave (PW) Doppler Continuous Wave (CW) Doppler SonoHD2 Noise Reduction SonoMB/MBe Image Compounding Steered CW Doppler Velocity Color Doppler Tissue Doppler Imaging (TDI)	B-mode Grayscale Imaging 3D/4D Grayscale Imaging Tissue Harmonic Imaging M-mode Anatomical M-Mode Color M-Mode Color Power Doppler Zoom Combination Modes Pulsed Wave (PW) Doppler Continuous Wave (CW) Doppler SonoRes/SonoHD Noise Reduction SonoMB Image Compounding Steered CW Doppler Velocity Color Doppler Tissue Doppler Imaging (TDI)
PW Doppler	Not available	Available	Available
CW Doppler	Not available	Available	Available
Patient Contact Materials	Transducers: Cycology Polycarbonate Polysulfone UDEL P1700 Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane Needle Guides: Acetal copolymer Acrylonitrile-butadien-styrene (ABS)	Transducers: Cycology Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane Needle Guides: Acetal copolymer Acrylonitrile-butadien-styrene (ABS)	Transducers: Acrylonitrile-butadien-styrene (ABS) Cycology Dow Medical Adhesive, Type A Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane Needle Guides: Acetal copolymer Acrylonitrile-butadien-styrene (ABS)
System Characteristics	SII: Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD 3 USB ports Dimension: 11.5"(W) x 17.6" (L) x 4.8"(H) Weight: 12.6 lbs System operates via battery or AC power 100 – 240V options, 50/60 Hz, 15VDC output Various obstetrical, cardiac, volume, and M-mode measurement and calculation	Edge II: Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD 2 USB ports Dimensions: 12.8"(W) x 12.1" (L) x 2.5"(H) Weight: 9.0 lbs System operates via battery or AC power 100 – 240V options, 50/60 Hz, 15VDC output Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and	S Series: Beamformer 128/128 using SA (configurable) Hand held display and control Single 10.4" Liquid Crystal Display (LCD) 256 gray shades on LCD 3 USB ports Dimensions: 11.6"(W) x 15.1" (L) x 6.1"(H) Weight: 8.5 lbs System operates via battery or AC power 100 – 240V options, 50/60 Hz, 15VDC output Various obstetrical, cardiac, volume, and M-mode measurement and calculation

Feature	SonoSite SII Ultrasound System (This submission)	SonoSite Edge II Ultrasound System (K153626)	SonoSite S Series Ultrasound System (K130173)
	packages Wireless 802.11 support for image transfer	calculation packages ECG acquisition and display capabilities CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Wireless 802.11 support for image transfer	packages Wireless 802.11 support for image transfer
510(k) Track	Track 3	Track 3	Track 3

7) Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The SonoSite SII Ultrasound System has been evaluated for electrical, thermal, mechanical, and EMC safety. Additionally, cleaning/disinfection, biocompatibility, and acoustic output have been evaluated, and the device has been found to conform to applicable mandatory medical device safety standards. Assurance of quality was established by employing the following elements of product development but were not limited to: Design Phase Reviews, Risk Assessment, Requirements Development, and Verification and Validation.

The SonoSite SII Ultrasound System is designed to comply with the following FDA recognized standards.

Reference No.	Title
ISO 10993-1	AAMI / ANSI / ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
IEC 60601-1	AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2	AAMI / ANSI / IEC 60601-1-2:2007(R)2012, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
IEC 60601-1-6	IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-37	IEC 60601-2-37:2007 Edition 2.0 2007-08, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	AAMI / ANSI / IEC 62304:2006, Medical device software - Software life cycle processes
IEC 62359	IEC 62359 Edition 2.0 2010-10-10, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields [Including: Technical corrigendum 1 (2011)]
ISO 14971	ISO 14971:2007, Medical devices - Application of risk management to medical devices
NEMA UD 2-2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

Summary of Clinical Tests:

The SonoSite SII Ultrasound System and transducers, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

8) Conclusion:

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance. The SonoSite SII system and predicates meet FDA requirements for Track 3 devices, share indications for use, have biosafety equivalence, and conform to applicable electromedical device safety standards. FUJIFILM SonoSite, Inc. believes that the SonoSite SII Ultrasound System is substantially equivalent with regard to safety and effectiveness to the predicate devices.