



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FUJIFILM SonoSite, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

April 19, 2016

Re: K160674
Trade/Device Name: FUJIFILM SonoSite Vevo MD Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, IYO
Dated: March 28, 2016
Received: March 29, 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 above the typed name and title.

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)

~~FDB~~ K160674

Device Name

FUJIFILM SonoSite Vevo MD Imaging System

Indications for Use (Describe)

The Vevo MD Imaging System is a general purpose imaging system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body.

Specific clinical applications and exam types include:

Abdominal

Pediatric

Small Organ (breast, thyroid, testicles, prostate)

Musculoskeletal (conventional)

Musculoskeletal (superficial)

Peripheral vessel

Dermatological

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
PRASStaff@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."

Table 1.3.1: Diagnostic Ultrasound Indications for Use Form – FUJIFILM SonoSite Vevo MD Imaging System

System:	FUJIFILM SonoSite Vevo MD Imaging System						
Transducer:	NA						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B (2D)	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	N	N			N	B(2D)+CD, B(2D)+M	1,2
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N			N	B(2D)+CD, B(2D)+M	1,2
Small Organ (breast, thyroid, testicles, prostate)	N	N			N	B(2D)+CD, B(2D)+M	1,2
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
Musculo-skel. (Superfic.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N			N	B(2D)+CD, B(2D)+M	1,2
Other (spec.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
DERMATOLOGY							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

1: The Vevo MD Imaging System uses ultra high frequency (UHF) series transducers that limit the imaging depth. For this reason imaging of abdominal organs or non-superficial musculoskeletal structure may be limited to neonatal and small pediatric patients and all imaging is limited to the maximum imaging depth of the transducer as indicated in the specifications for each transducer.

2: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures.

Table 1.3.2: Diagnostic Ultrasound Indications for Use Form – FUJIFILM Vevo MD UHF-22 Ultrasound Transducer

System:	FUJIFILM SonoSite Vevo MD Imaging System						
Transducer:	UHF-22						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B (2D)	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	N	N			N	B(2D)+CD, B(2D)+M	1,2
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N			N	B(2D)+CD, B(2D)+M	1,2
Small Organ (breast, thyroid, testicles, prostate) ¹	N	N			N	B(2D)+CD, B(2D)+M	1,2
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
Musculo-skel. (Superfic.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N			N	B(2D)+CD, B(2D)+M	1,2
Other (spec.)							
DERMATOLOGY							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

1: The Vevo MD Imaging System uses ultra high frequency (UHF) series transducers that limit the imaging depth. For this reason imaging of abdominal organs or non-superficial musculoskeletal structure may be limited to neonatal and small pediatric patients and all imaging is limited to the maximum imaging depth of the transducer as indicated in the specifications for each transducer.

2: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures.

Table 1.3.3: Diagnostic Ultrasound Indications for Use Form – Fujifilm Vevo MD UHF-48 Ultrasound Transducer

System:	FUJIFILM SonoSite Vevo MD Imaging System						
Transducer:	UHF-48						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B (2D)	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N			N	B(2D)+CD, B(2D)+M	1,2
Small Organ (breast, thyroid, testicles, prostate) ¹	N	N			N	B(2D)+CD, B(2D)+M	1,2
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
Musculo-skel. (Superfic.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N			N	B(2D)+CD, B(2D)+M	1,2
Other (spec.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
DERMATOLOGY							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

1: The Vevo MD Imaging System uses ultra high frequency (UHF) series transducers that limit the imaging depth. For this reason imaging of abdominal organs or non-superficial musculoskeletal structure may be limited to neonatal and small pediatric patients and all imaging is limited to the maximum imaging depth of the transducer as indicated in the specifications for each transducer.

2: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedure.

Table 1.3.4: Diagnostic Ultrasound Indications for Use Form – Fujifilm Vevo MD UHF-70 Ultrasound Transducer

System:	FUJIFILM SonoSite Vevo MD Imaging System						
Transducer:	UHF-70						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B (2D)	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N			N	B(2D)+CD, B(2D)+M	1,2
Small Organ (breast, thyroid, testicles, prostate) ¹	N	N			N	B(2D)+CD, B(2D)+M	1,2
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
Musculo-skel. (Superfic.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N			N	B(2D)+CD, B(2D)+M	1,2
Other (spec.)	N	N			N	B(2D)+CD, B(2D)+M	1,2
DERMATOLOGY							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

1: The Vevo MD Imaging System uses ultra high frequency (UHF) series transducers that limit the imaging depth. For this reason imaging of abdominal organs or non-superficial musculoskeletal structure may be limited to neonatal and small pediatric patients and all imaging is limited to the maximum imaging depth of the transducer as indicated in the specifications for each transducer.

2: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedure.

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: Scott E. Paulson
Sr. Director, Regulatory Affairs and Quality Systems
E-mail: Scott.Paulson@sonosite.com
Telephone: (425) 951-6926
Facsimile: (425) 491-8356
Date prepared: December 26 , 2015

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 Vevo MD™ Imaging System (*subject to change*)

Classification Names

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

3) Identification of the predicate or legally marketed device:

SonoSite X-Porte ultrasound system (K133134) (Primary Predicate)
EpiScan I-200 (k062571) (Secondary predicate)

4) Device Description:

The Vevo MD system is a high frequency general purpose, software controlled, diagnostic Imaging System used to acquire and display high-resolution, real-time ultrasound data in 2D, Color Doppler, and M-Mode. The Vevo MD System is comprised of transducers responsible for ultrasound signal generation and recording, and a main unit that controls the transducers, processes the acoustic data, and processes and displays images.

5) Intended Use:

The intended uses of the SonoSite Vevo MD Imaging System as defined by FDA guidance documents, are:

Abdominal
Pediatric
Small Organ (breast, thyroid, testicles, prostate)
Musculo-skel. (Convent.)
Musculo-skel. (Superfic.)
Peripheral vessel
Dermatological

6) Technological Characteristics:

SonoSite Vevo MD and X-Porte Ultrasound Systems are both Track 3 devices that employ the same fundamental scientific technology. A comparison table is provided below.

Feature	SonoSite Vevo MD Imaging System (this submission)	SonoSite X-Porte Ultrasound System K133134	EpiScan I-200 K062571
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	High resolution ultrasound imaging for wounds, superficial musculoskeletal diagnosis and assessment, plastic/reconstructive surgery planning and assessment, dermatological assessment and diagnosis, and aesthetic application
Transducer Types Available	Linear Array	Linear Array Curved Linear Array Intracavitary Phased Array	Scanning Element

Feature	SonoSite Vevo MD Imaging System (this submission)	SonoSite X-Porte Ultrasound System K133134	EpiScan I-200 K062571
Transducer Center Frequency	15-49MHz	1.0 – 15.0 MHz	20-50MHz
Acoustic Output Display & FDA Limits	MI Output Display TI Output Display	Display Feature for Higher Outputs MI Output Display TI Output Display	Not displayed
Modes of Operation	B-mode (2-D Grayscale Imaging) Color Doppler Combination Modes M-mode	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 Greyscale or color imaging.
DICOM	DICOM 3.0 Store, Modality Worklist, Perform Procedure Step (PPS), Storage Commitment	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step (PPS), Storage Commitment	Not available
IMT Measurement	Manual Measurement available on the ultrasound system itself.	Not available	Not available
#Transmit Channels	64 digital channels	128 digital channels	1 channel

Feature	SonoSite Vevo MD Imaging System (this submission)	SonoSite X-Porte Ultrasound System K133134	EpiScan I-200 K062571
#Receive Channels	64 digital channels	64 digital channels (128 digital channels using Synthetic Aperture)	1 channel
510(k) Track	Track 3	Track 3	Track 1

7) Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Vevo MD Imaging 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: Design Phase Reviews, Risk Assessment, Requirements Development, System and Software Verification, Hardware Verification, Safety Compliance Verification, Clinical Validation. All patient contact materials are biocompatible and are materials that are already used in the predicate device or meet 10993.

The Vevo MD Imaging System is designed to comply with the following voluntary standards.

Reference No.	Recognition No.	Title
AAMI/ANSI/ISO 10993-1	2-156	ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
IEC 60601-1	19-5	AAMI / ANSI ES60601-1:2005/(R)2012 And 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). (General II (ES/EMC))
IEC 60601-1-2	19-1	IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
IEC 60601-2-37	12-209	IEC 60601-2-37:2007, Particular Requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

Reference No.	Recognition No.	Title
NEMA UD 2-2004	12-105	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD 3-2004	12-100	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine

Summary of Clinical Tests:

The Vevo MD Imaging 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 Vevo MD device and predicate both conform to applicable electromedical device safety standards with compliance verified through independent evaluation. The Vevo MD device and predicate both meet FDA requirements for Track 3 devices, share indications for use, have biosafety equivalence and are manufactured using the same ISO 13485 quality system. FUJIFILM SonoSite, Inc. believes that the Vevo MD Imaging System is substantially equivalent with regard to safety and effectiveness to the predicate device(s).