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

March 15, 2019

Re: K190476
Trade/Device Name: FUJIFILM SonoSite Vevo MD Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: February 25, 2019
Received: February 27, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K190476

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
Dermatological
Musculoskeletal (conventional)
Musculoskeletal (superficial)
Neonatal Cephalic
Ophthalmic
Pediatric
Peripheral vessel
Small Organ (breast, thyroid, testicles, prostate)

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:

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Office of Chief Information Officer
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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."

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

System:	Vevo MD Imaging System							
Transducer:	**UHF22, UHF48, UHF70**							
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:							
Clinical Application	**Mode of Operation**							
	2D	M	PWD	CWD	Color Doppler (CD)	Power Doppler (CPD)	Combined (Spec.)	Other (Spec.)
Ophthalmic	N							1,2,3
Fetal								
Abdominal	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2,3
Intra-operative (Abdominal organs and vascular)								
Intra-operative (Neuro.)								
Laparoscopic								
Pediatric	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1, 2
Neonatal Cephalic	N	N	N		N	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1, 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-skel. (Convent.)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Musculo-skel. (Superfic.)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Intra-luminal								
Other (spec.)								
Cardiac Adult								
Cardiac Pediatric								
Trans-esophageal (card.)								
Other (spec.)								
Peripheral vessel	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Other (Dermatology)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2

N= New Indicated Imaging Examination P=Previously Indicated Imaging Examination

Additional Comments/Other (Spec.):

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.

3: Abdominal and Ophthalmic clinical applications are indications for use for the UHF22 transducer only

System:	Vevo MD Imaging System							
Transducer:	**UHF22**							
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 (CD)	Power Doppler (CPD)	Combined (Spec.)	Other (Spec.)
Ophthalmic	N							1,2,3
Fetal								
Abdominal	P	P	N		P	N	2D+CD, 2D+M, 2D+ CPD, 2D+PWD	1,2,3
Intra-operative (Abdominal organs and vascular)								
Intra-operative (Neuro.)								
Laparoscopic								
Pediatric	P	P	N		P	N	2D+CD, 2D+M, 2D+ CPD, 2D+PWD	1,2
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1, 2
Neonatal Cephalic	N	N	N		N	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1, 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-skel. (Convent.)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Musculo-skel. (Superfic.)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Intra-luminal								
Other (spec.)								
Cardiac Adult								
Cardiac Pediatric								
Trans-esophageal (card.)								
Other (spec.)								
Peripheral vessel	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Other (Dermatology)	N	N	N		N	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2

N= New Indicated Imaging Examination P=Previously Indicated Imaging Examination

Additional Comments/Other (Spec.):

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.

3: Abdominal and Ophthalmic clinical applications are indications for use for the UHF22 transducer only

System:	Vevo MD Imaging System							
Transducer:	**UHF48**							
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 (CD)	Power Doppler (CPD)	Combined (Spec.)	Other (Spec.)
Ophthalmic								
Fetal								
Abdominal								
Intra-operative (Abdominal organs and vascular)								
Intra-operative (Neuro.)								
Laparoscopic								
Pediatric	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		P	N	2D+CD, 2D+M, 2D+ CPD, 2D+PWD	1, 2
Neonatal Cephalic	N	N	N		N	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1, 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-skel. (Convent.)	P	P	N		P	N	2D+CD, 2D+M, 2D+ CPD, 2D+PWD	1,2
Musculo-skel. (Superfic.)	P	P	N		P	N	2D+CD, 2D+M, 2D+ CPD, 2D+PWD	1,2
Intra-luminal								
Other (spec.)								
Cardiac Adult								
Cardiac Pediatric								
Trans-esophageal (card.)								
Other (spec.)								
Peripheral vessel	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Other (Dermatology)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2

N= New Indicated Imaging Examination P=Previously Indicated Imaging Examination

Additional Comments/Other (Spec.):

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.

System:	Vevo MD Imaging System							
Transducer:	**UHF70**							
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 (CD)	Power Doppler (CPD)	Combined (Spec.)	Other (Spec.)
Ophthalmic								
Fetal								
Abdominal								
Intra-operative (Abdominal organs and vascular)								
Intra-operative (Neuro.)								
Laparoscopic								
Pediatric	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1, 2
Neonatal Cephalic	N	N	N		N	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1, 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-skel. (Convent.)	P	P	N		P	N	2D+CD, 2D+M, 2D+ CPD, 2D+PWD	1,2
Musculo-skel. (Superfic.)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Intra-luminal								
Other (spec.)								
Cardiac Adult								
Cardiac Pediatric								
Trans-esophageal (card.)								
Other (spec.)								
Peripheral vessel	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2
Other (Dermatology)	P	P	N		P	N	2D+CD, 2D+M, 2D+CPD, 2D+PWD	1,2

N= New Indicated Imaging Examination P=Previously Indicated Imaging Examination

Additional Comments/Other (Spec.):

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.

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510(K) Summary-K190476

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: Anoush Frankian
Sr. Manager, Regulatory Affairs
E-mail: anoush.frankian@fujifilm.com
Telephone: (425) 951-6824
Facsimile: (425) 491-8356
Date prepared: February 11, 2019

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

FUJIFILM SonoSite Vevo MD Imaging System

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:

FUJIFILM SonoSite Vevo MD Imaging System (K160674) (Primary Predicate)
SonoSite X-Porte ultrasound system (K171437) (Reference Predicate)

4) Device Description:

The Vevo MD Imaging System is a high frequency general purpose, software controlled, diagnostic imaging system used to acquire ad display high-resolution, real-time ultrasound data in 2D, Color Doppler, Power Doppler, PW Doppler and M-Mode. The Vevo MD Imaging 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 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
Dermatological
Musculoskeletal (conventional)
Musculoskeletal (superficial)
Neonatal Cephalic
Ophthalmic
Pediatric
Peripheral vessel
Small Organ (breast, thyroid, testicles, prostate)

6) Technological Characteristics:

The Vevo MD Imaging System subject of this submission and its primary predicate Vevo MD Imaging System (K160674) and reference predicate X-Porte (K171437) are all Track 3 devices that employ the same fundamental scientific technology. A comparison table is provided below.

Feature	**SonoSite VevoMD Ultrasound System (this submission)**	**SonoSite VevoMD Ultrasound System (K160674)**	**SonoSite X-Porte Ultrasound System (K171437)**
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
Transducer Types Available	Linear Array	Linear Array	Linear Array Curved Linear Array Intracavitary Phased Array
Transducer Center Frequency	15-49MHz	15-49MHz	1.0 – 15.0 MHz

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Feature	SonoSite VevoMD Ultrasound System (this submission)	SonoSite VevoMD Ultrasound System (K160674)	SonoSite X-Porte Ultrasound System (K171437)
Acoustic Output Display & FDA Limits	MI Output Display TI Output Display	MI Output Display TI Output Display	Display Feature for Higher Outputs MI Output Display TI Output Display
Modes of Operation	2D Mode, Color Doppler, M-Mode, Power Doppler, PW Doppler	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)

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Feature	SonoSite VevoMD Ultrasound System (this submission)	SonoSite VevoMD Ultrasound System (K160674)	SonoSite X-Porte Ultrasound System (K171437)
DICOM	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step (PPS), Storage Commitment	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step (PPS), Storage Commitment	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step (PPS), Storage Commitment
IMT Measurement	Manual Measurement available on the ultrasound system itself.	Manual Measurement available on the ultrasound system itself.	Not available
#Transmit Channels	64 digital channels	64 digital channels	128 digital channels
#Receive Channels	64 digital channels	64 digital channels	64 digital channels (128 digital channels using Synthetic Aperture)
510(k) Track	Track 3	Track 3	Track 3

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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	2-220	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
IEC 60601-1	19-4	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	19-8	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests (Edition 4)
IEC 60601-2-37	12-293	Particular Requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (Edition 2.1)
IEC 62359	12-316	Ultrasonic - Field Characterization - Test Methods For The Determination Of Thermal And Mechanical Indices Related To Medical Diagnostic Ultrasonic Fields
IEC 62304	13-79	Medical Device Software - Software Life Cycle Processes
ISO 14971	5-40	Medical devices - Application of risk management to medical devices
NEMA UD 2	12-105	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

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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 Ultrasound System is substantially equivalent with regard to safety and effectiveness to the predicate device(s).