April 10, 2020

Siemens Medical Solutions USA, Inc.
% Shruti Arora
Regulatory Affairs Specialist
685 East Middlefield Road
MOUNTAIN VIEW CA 94043

Re: K200644
Trade/Device Name: ACUSON Freestyle™ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, OIJ, ITX
Dated: March 10, 2020
Received: March 11, 2020

Dear Shruti Arora:

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 and Part 809); 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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200644

Device Name

ACUSON Freestyle Diagnostic Ultrasound System

Indications for Use *(Describe)*

The ACUSON Freestyle Ultrasound System is intended for diagnostic imaging or fluid flow analysis of the human body performed by an appropriately trained healthcare professional in a healthcare setting for the following conditions: Abdominal, Pediatric, Small Organ, Peripheral Vessel, Musculoskeletal (Conventional), Musculoskeletal (Superficial).

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.

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"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."

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **ACUSON Freestyle™ Diagnostic Ultrasound System**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) **(Note 2)**	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P				P	P			
Intraoperative										
Intraoperative Neurological										
Pediatric		P				P	P			
Small Organ **(Note 1)**		P				P	P			
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P				P	P			
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P			
Musculo-skeletal Superficial		P	P	P		P	P			
Other (specify)										

N = new indication; P = previously cleared by K162417, Blank = Not Claimed

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis etc.
Note 2 B-mode and PWD mode or Color Doppler and PW mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **L8-3 Linear Array Transducer**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) **(Note 2)**	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P				P	P			
Intraoperative										
Intraoperative Neurological										
Pediatric		P				P	P			
Small Organ **(Note 1)**		P				P	P			
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P				P	P			
Laparoscopic										
Musculo-skeletal Conventional		P				P	P			
Musculo-skeletal Superficial		P				P	P			
Other (specify)										

N = new indication; P = previously cleared by K162417, Blank = Not Claimed

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis etc.
Note 2 B-mode and PWD mode or Color Doppler and PW mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **L13-5 Linear Array Transducer**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) **(Note 2)**	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P				P	P			
Intraoperative										
Intraoperative Neurological										
Pediatric		P				P	P			
Small Organ **(Note 1)**		P				P	P			
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P				P	P			
Laparoscopic										
Musculo-skeletal Conventional		P				P	P			
Musculo-skeletal Superficial		P				P	P			
Other (specify)										

N = new indication; P = previously cleared by K162417, Blank = Not Claimed

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis etc.
Note 2 B-mode and PWD mode or Color Doppler and PW mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **L17-5 Linear Array Transducer**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) **(Note 2)**	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N				N	N			
Intraoperative										
Intraoperative Neurological										
Pediatric		N				N	N			
Small Organ **(Note 1)**		N				N	N			
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		N				N	N			
Laparoscopic										
Musculo-skeletal Conventional		N				N	N			
Musculo-skeletal Superficial		N				N	N			
Other (specify)										

N = new indication; P = previously cleared by K162417, Blank = Not Claimed

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis etc.
Note 2 B-mode and PWD mode or Color Doppler and PW mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices
510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **C5-2 Curvilinear Array Transducer**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) **(Note 2)**	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P				P	P			
Intraoperative										
Intraoperative Neurological										
Pediatric		P				P	P			
Small Organ **(Note 1)**		P				P	P			
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P				P	P			
Laparoscopic										
Musculo-skeletal Conventional		P				P	P			
Musculo-skeletal Superficial		P				P	P			
Other (specify)										

N = new indication; P = previously cleared by K162417, Blank = Not Claimed

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis etc.
Note 2 B-mode and PWD mode or Color Doppler and PW mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices
510(k)_____

510(K) SUMMARY

This summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21CFR §807.92.

Date: March 10th, 2020

1. Sponsor:
Siemens Medical Solutions USA, Inc.,
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

Contact Person:
Shruti Arora
Tel: (425) 375-6890

2. Device Name: ACUSON Freestyle™ Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class:	II
Review Category:	Tier II
Classification Panel:	Radiology

Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
		90-OIJ
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Manufacturing Site:
Siemens Medical Solutions USA, Inc.
5168 Campus Drive
Plymouth Meeting, PA 19462, UNITED STATES

3. Legally Marketed Predicate Devices

The ACUSON Freestyle Diagnostic Ultrasound System; v4.1 (VA41A) is a portable ultrasound imaging system with accessories and proprietary software. This subject device VA41A is a modification to the predicate device and is substantially equivalent to the company's legally marketed device, ACUSON Freestyle 4.0 (VA40A) previously cleared as represented below:

Predicate Device	510(k) Number	Clearance Date
ACUSON Freestyle™ Ultrasound System (v4.0)	K162417	09/28/2016

4. Device Description

The ACUSON Freestyle™ Diagnostic Ultrasound System is a portable ultrasound imaging system where the system operates with linear and curvilinear array transducers. These transducers may be used in a wireless mode or using a probe adaptor cable and is capable of the following modes (these modes below can be operated in combination or individually):

- B-Mode
- Color Doppler Mode
- Amplitude Doppler Mode

The ACUSON Freestyle™ Diagnostic Ultrasound System includes a main unit console with user interface controls, a 15-inch video display, and system electronics. The main unit weighs approximately 10.5 pounds and is 13.2 inches high, 14.7 inches wide, and 5 inches deep. The system may be mounted on a small roll stand, monitor arm, or tabletop. An optional external receiving antenna can be mounted to the unit console, this provides better line of sight to the wireless transducers. The system provides an intuitive and easy-to operate user interface. It has a compact and portable design and offers DICOM archival and networking capability.

The ACUSON Freestyle Ultrasound System is intended for diagnostic imaging or fluid flow analysis performed by an appropriately trained healthcare professional in a healthcare setting for the following conditions: Abdominal, Pediatric, Small Organ, Peripheral Vessel, Musculoskeletal (Conventional), Musculoskeletal Superficial. The system also provides the ability to measure anatomical structures using distance, ellipse and area measurements. This information may be used adjunctively with other medical data obtained by a physician for clinical diagnostic purposes.

5. Intended Use and Indications for Use Statement

The ACUSON Freestyle Ultrasound System is intended for diagnostic imaging or fluid flow analysis performed by an appropriately trained healthcare professional in a healthcare setting for the following conditions: Abdominal, Pediatric, Small Organ, Peripheral Vessel, Musculoskeletal (Conventional), Musculoskeletal Superficial.

6. Comparison of Technological Characteristics with the Predicate Device

The modified ACUSON Freestyle Diagnostic Ultrasound System is substantially equivalent to the company's own previously cleared ACUSON Freestyle, VA40A (K162417) with regard to both intended use and technological characteristics. Both the modified ultrasound system under this review and the predicate ultrasound system function in the same manner as all diagnostic ultrasound systems and transducers.

The submission device differs from the predicated devices as following:

- The modified ACUSON Freestyle Diagnostic Ultrasound System includes the addition of the L17-5 transducer. The L17-5 transducer is substantially equivalent to the L13-5 in its indications for use and fundamental scientific technology where L13-5 was cleared as a part of the ACUSON Freestyle VA40A (v4.0) under K162417 . L17-5 is a modified version of L13-5 with higher frequency capability to improve near field resolution.
- The modified ACUSON Freestyle Diagnostic Ultrasound System updated the indications for use statement (Intended use) to delete the following indications: Fetal, Cardiac, Neonatal Cephalic, Intraoperative, Intraoperative neurological and rephrased to include

the operator qualification and device use setting (previously cleared on the predicate device under K162417).

- The modified ACUSON Freestyle Diagnostic Ultrasound System incorporates other device usability enhancements and improved imaging features: Dual screen capability (viewing two imaging areas side by side), Import/export system settings, inclusion of digital video output (to support use of the device in interventional suites without the need for video converters), product data security (prevent unauthorized access to system or patient data) and software updates to enhance the user workflow and security requirements..

The foundation of the ACUSON Freestyle (this submission) is the ACUSON Freestyle (K162417) which will be updated with the VA41A software version supporting all transducers (L8-3, C5-2, L13-5 and L17-5) and all device clinical application. The ACUSON Freestyle with software version VA41A is substantially equivalent to the predicate device with regard to both the intended use, indications for use and technological characteristics. The table below compares the technological characteristics between the submission device and the predicate devices.

List of Technological characteristics and SE comparison

	Predicate Device (K162417)		Proposed/Submission Device		
Feature / Characteristic	**ACUSON Freestyle VA40A (v4.0)**	**ACUSON Freestyle Elite VA40A (v4.0)**	**ACUSON Freestyle VA41A (v4.1)**	**ACUSON Freestyle Elite VA41A (v4.1)**	***SE Comparative Conclusion***
Device Classification (Regulation, Device Class, Product code and panel)	Regulatory Class: II Review Category: Tier II Classification Panel: 90, Radiology Ultrasonic Pulsed Doppler Imaging System; 21 CFR # 892.1550 Product Code: IYN Ultrasonic Pulsed Echo Imaging System; 21 CFR # 892.1560 Product Code: IYO Ultrasonic Pulsed Echo Imaging System; 21 CFR # 892.1560 Product Code: OIJ Diagnostic Ultrasound Transducer; 21 CFR # 892.1570 Product Code: ITX		Regulatory Class: II Review Category: Tier II Classification Panel: 90, Radiology Ultrasonic Pulsed Doppler Imaging System; 21 CFR # 892.1550 Product Code: IYN Ultrasonic Pulsed Echo Imaging System; 21 CFR # 892.1560 Product Code: IYO Ultrasonic Pulsed Echo Imaging System; 21 CFR # 892.1560 Product Code: OIJ Diagnostic Ultrasound Transducer; 21 CFR # 892.1570 Product Code: ITX		IDENTICAL
Indications for Use:					
▪ Fetal	√	√	-	-	MODIFIED (Indication deleted)
▪ Abdominal	√	√	√	√	IDENTICAL
▪ Pediatric	√	√	√	√	IDENTICAL
▪ Small Organ[1]	√	√	√	√	IDENTICAL
▪ Cardiac	√	√	-	-	MODIFIED (Indication deleted)

[1] Includes Breast, Thyroid, testicles and lymph nodes.

	Predicate Device (K162417)		Proposed/Submission Device		
Feature / Characteristic	**ACUSON Freestyle VA40A (v4.0)**	**ACUSON Freestyle Elite VA40A (v4.0)**	**ACUSON Freestyle VA41A (v4.1)**	**ACUSON Freestyle Elite VA41A (v4.1)**	***SE Comparative Conclusion***
▪ Intraoperative	√	√	-	-	MODIFIED (Indication deleted)
▪ Intraoperative Neurological	√	√	-	-	MODIFIED (Indication deleted)
▪ Peripheral vessel	√	√	√	√	IDENTICAL
▪ Musculo-skeletal (conventional)	√	√	√	√	IDENTICAL
▪ Musculo-skeletal (superficial)	√	√	√	√	IDENTICAL
▪ Neonatal cephalic	√	√	-	-	MODIFIED (Indication deleted)
Imaging Modes:					
▪ B	√	√	√	√	IDENTICAL
▪ Color Doppler	√	√	√	√	IDENTICAL
▪ Power (Amplitude) Doppler	√	√	√	√	IDENTICAL
Transducer Frequencies Supported:					
▪ L8-3 (Linear)	√(3.0 – 8.0) MHz	√(3.0 – 8.0) MHz	√(3.0 – 8.0) MHz	√(3.0 – 8.0) MHz	IDENTICAL
▪ L13-5 (Linear)	√(5.0 – 13.0) MHz	√(5.0 – 13.0) MHz	√(5.0 – 13.0) MHz	√(5.0 – 13.0) MHz	IDENTICAL
▪ C5-2 (Curvilinear)	√(2.0 – 5.0) MHz	√(2.0 – 5.0) MHz	√(2.0 – 5.0) MHz	√(2.0 – 5.0) MHz	IDENTICAL
▪ L17-5 (Linear)	-	-	√(5.0 – 17.0) MHz *New*	√(5.0 – 17.0) MHz *New*	MODIFIED (introduction of L17-5 transducer)
Imaging functions, Controls and Display:					
▪ Multi-Hertz multiple frequency imaging	√	√	√	√	IDENTICAL
▪ Beam-free synthetic aperture and Pixelformer image	√	√	√	√	IDENTICAL
▪ Spatial Compounding	√	√	√	√	IDENTICAL
▪ Speckle Filter	√	√	√	√	IDENTICAL
▪ Time/Gain compensation function	√	√	√	√	IDENTICAL
▪ Auto Send	√	√	√	√	IDENTICAL
▪ Auto Study Management	√	√	√	√	IDENTICAL

	Predicate Device (K162417)		Proposed/Submission Device		
Feature / Characteristic	**ACUSON Freestyle VA40A (v4.0)**	**ACUSON Freestyle Elite VA40A (v4.0)**	**ACUSON Freestyle VA41A (v4.1)**	**ACUSON Freestyle Elite VA41A (v4.1)**	***SE Comparative Conclusion***
▪ Multiple angle needle visualization (Needle V)	√ (Optional)	√	√	√	IDENTICAL
▪ Measurements (Distance, Area, Elliptical)	√	√	√	√	IDENTICAL
▪ Trapezoidal (Wide) Imaging	√	√	√	√	IDENTICAL
▪ Dual Mode	-	-	√ *New*	√ *New*	MODIFIED
▪ Split Mode	-	-	√ *New*	√ *New*	MODIFIED
▪ **Cine Capture**					
- Clip Store length	Upto 30 secs	Upto 30 secs	Upto 30 secs	Upto 30 secs	IDENTICAL
- Clip replay on system	√	√	√	√	IDENTICAL
▪ Artis Patient Synchronization	-	√ (Optional)	-	√	IDENTICAL
▪ Artis Access (includes Artis patient synchronization, external antenna & Freestyle Elite to Artis Large Display mounting)	-	√ (Optional)	-	√	IDENTICAL
Wireless Transducer					
▪ Wireless Ultrasound Image Transmission	B, Color, Amplitude	B, Color, Amplitude	B, Color, Amplitude	B, Color, Amplitude	IDENTICAL
▪ Meets FCC Part 15 Subpart B: Unintentional Radiators	√	√	√	√	IDENTICAL
▪ Meets FCC Part 15 Subpart C: Intentional Radiators	√	√	√	√	IDENTICAL
▪ Meets FCC Part 15 Subpart F: Ultra-Wideband Operation	√	√	√	√	IDENTICAL
▪ Meets FCC Part 95 (WMTS)	-	-	-	-	IDENTICAL
▪ Frequency Range RF Transmitter	7.5-8.5 GHz	7.5-8.5 GHz	7.5-8.5 GHz	7.5-8.5 GHz	IDENTICAL
▪ Lithium Ion Battery Operation	√	√	√	√	IDENTICAL
Connectivity					

	Predicate Device (K162417)		Proposed/Submission Device		
Feature / Characteristic	**ACUSON Freestyle VA40A (v4.0)**	**ACUSON Freestyle Elite VA40A (v4.0)**	**ACUSON Freestyle VA41A (v4.1)**	**ACUSON Freestyle Elite VA41A (v4.1)**	***SE Comparative Conclusion***
▪ Wireless network	√	√	√	√	IDENTICAL
▪ External Antenna	√ (Optional)	√ (Optional)	√ (Optional)	√ (Optional)	IDENTICAL
▪ DICOM Compatibility (Storage, Commit, MWL, MPPS & Media)	√ (Optional)	√	√ (Optional)	√	IDENTICAL
▪ Mobile Link App (connection)	√	√	√	√	IDENTICAL
Monitor: 15 inch (38.1 cm) high-bright LED LCD	√	√	√	√	IDENTICAL
Software Operating System (GreenHills Integrity RTOS**)**	√	√	√	√	IDENTICAL
Output Display Standard (Track 3)	√	√	√	√	IDENTICAL
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	IDENTICAL
UL 60601-1 Certified	√	√	√	√	IDENTICAL

Substantial Equivalence Conclusion: From the information provided in table above; it is understood that the subject device does not introduce any new technology and/or indications of use; therefore, ACUSON Freestyle VA41A is considered substantially equivalent to the predicate device; the ACUSON Freestyle VA40A.

7. Summary of Design Control Activities and Performance Data

The ACUSON Freestyle Diagnostic Ultrasound System is verified and validated according to the design control requirements of 21 CFR 820 and ISO 13485:2016 quality system standards. The subject device had been subjected to extensive safety and performance testing before release to ensure the device meets all its specifications. The quality assurance measures applied to the design and development of the subject device include, but not limited to risk analysis, verification and validation, product specifications and design reviews.

Software Verification and Validation Testing:

Software documentation for a Moderate Level of Concern software per FDA's guidance document "Guidance for the Content of Premarket Submission for Software contained in Medical Devices" issued on May 11, 2005 is included as part of this submission.

Non-Clinical/Clinical Testing Summary:

The device has been evaluated for acoustic output, cleaning, and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety and have been found to conform to applicable medical device safety standards. The systems comply with the following voluntary standards:

- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- Refer to the table below for the Safety/EMC and Biocompatibility standards.

Compliance Summary to Voluntary Standards

Recognition Number	Product Area	Title of Standard	Publication Date	Standard development organization
19-4	General II (ES/ EMC)	ANSI AAMI 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)	07/09/2014	ANSI AAMI
19-8	General II (ES/ EMC)	IEC 60601-1-2 Edition 4.0 2014-02 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	09/17/2018	ANSI AAMI IEC
12-293	Radiology	IEC 60601-2-37 Edition 2.1 2015 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	06/27/2016	IEC
12-316	Radiology	IEC 62359 Edition 2.1 2017-09 Consolidated Version – Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields	06/07/2018	IEC
5-89	General I (QS/ RM)	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment – Part 1-6: General requirements for basic safety and	06/27/2016	IEC

		essential performance – Collateral Standard: Usability		
13-79	Software/ Informatics	IEC 62304 Edition 1.1 2015-06 Consolidated Version Medical device software – Software life cycle processes.	01/14/2019	IEC
2-220	Biocompatibility	ISO 10993-1 Fourth edition 2009-10-15, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]	07/26/2016	ISO

Since the ACUSON Freestyle Diagnostic Ultrasound System is a class II device and uses the same technology and operating principles as existing predicate device, ACUSON Freestyle Ultrasound System (K162417), therefore clinical studies were not required to support substantial equivalence.

Further the device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a hazard analysis which identifies potential hazards and is conducted according to ISO 14971:2007 standard. These potential hazards are controlled during development, verification and validation testing for each of the device modifications. The complete risk analysis is available in the device risk hazard analysis report included as part of this submission.

9. Summary

Based on the information provided here in the summary and from the comparison of the device with predicate in table above; ACUSON Freestyle Diagnostic Ultrasound System (VA41A) has the same intended use (indications for use) as the predicate device; incorporates technological features of the predicate device cleared through premarket notification and performance testing indicates that no new issues of safety or effectiveness are raised.

Siemens Medical Solutions USA, Inc. considers the ACUSON Freestyle Diagnostic Ultrasound System VA41A (v4.1) to be substantially equivalent with respect to safety and effectiveness to the previously cleared predicate device for the U.S. market.