DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 28, 2016

SIEMENS MEDICAL SOLUTIONS, INC.
c/o Mr. MARK JOB
THIRD PARTY REVIEWER
REGULATORY TECHNOLOGY SERVICES LLC
1394 25TH STREET, NW
BUFFALO MN 55313

Re: K162417
Trade/Device Name: Acuson Freestyle Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 29, 2016
Received: August 30, 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,

Michael D. O'Hara For

Robert Ochs
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
ACUSON Freestyle™ Ultrasound System

Indications for Use *(Describe)*
The ACUSON Freestyle™ Ultrasound System is intended for diagnostic imaging or fluid flow analysis of the human body including: Fetal, Abdominal, Intraoperative, Intraoperative Neurological, Pediatric, Small Organ, Neonatal Cephalic, Cardiac, 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 (Per Appendix G, FDA Ultrasound Guidance)

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: Harmonic Imaging
Opthalmic										
Fetal		P				P	P			
Abdominal		P				P	P			
Intraoperative (Note 1)		P				P	P			
Intraoperative Neurological		P				P	P			
Pediatric		P				P	P			
Small Organ (Note 3)		P				P	P			
Neonatal Cephalic		P				P	P			
Adult Cephalic										
Cardiac		P				P	P			
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P				P	P			
Laparoscopic										
Musculo-skeletal Conventional		P				P	P			
Musculo-skeletal Superficial		P				P	P			
Other										

N=new indication, P = Previously Cleared, Blank: Not Claimed

Additional Comments:

Note 1: For example Cardiac

Note 2: B Mode and PWD mode, or Cardiac Doppler and PW Mode

Note 3: Breast, Testes, Thyroid, Penis

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known):

Device Name: **L8-3 Linear 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: Harmonic Imaging
Opthalmic										
Fetal		P				P	P			
Abdominal		P				P	P			
Intraoperative (Note 1)		P				P	P			
Intraoperative Neurological		P				P	P			
Pediatric		P				P	P			
Small Organ (Note 3)		P				P	P			
Neonatal Cephalic		P				P	P			
Adult Cephalic										
Cardiac		P				P	P			
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P				P	P			
Laparoscopic										
Musculo-skeletal Conventional		P				P	P			
Musculo-skeletal Superficial		P				P	P			
Other										

N=new indication, P = Previously Cleared, Blank: Not Claimed

Additional Comments:

Note 1: For example Cardiac

Note 2: B Mode and PWD mode, or color Doppler and PW Mode

Note 3: Breast, Testes, Thyroid, Penis

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known):

Device Name: **L12-5 Linear 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: Harmonic Imaging
Opthalmic										
Fetal		P				P	P			
Abdominal		P				P	P			
Intraoperative (Note 1)		P				P	P			
Intraoperative Neurological		P				P	P			
Pediatric		P				P	P			
Small Organ (Note 3)		P				P	P			
Neonatal Cephalic		P				P	P			
Adult Cephalic										
Cardiac		P				P	P			
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P				P	P			
Laparoscopic										
Musculo-skeletal Conventional		P				P	P			
Musculo-skeletal Superficial		P				P	P			
Other										

N=new indication, P = Previously Cleared, Blank: Not Claimed

Additional Comments:

Note 1: For example Cardiac

Note 2: B Mode and PWD mode, or color Doppler and PW Mode

Note 3: Breast, Testes, Thyroid, Penis

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known):

Device Name: **C5-2 Curvilinear 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: Harmonic Imaging
Opthalmic										
Fetal		P				P	P			
Abdominal		P				P	P			
Intraoperative (Note 1)		P				P	P			
Intraoperative Neurological		P				P	P			
Pediatric		P				P	P			
Small Organ (Note 3)		P				P	P			
Neonatal Cephalic		P				P	P			
Adult Cephalic										
Cardiac		P				P	P			
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P				P	P			
Laparoscopic										
Musculo-skeletal Conventional		P				P	P			
Musculo-skeletal Superficial		P				P	P			
Other										

N=new indication, P = Previously Cleared, Blank: Not Claimed

Additional Comments:

Note 1: For example Cardiac

Note 2: B Mode and PWD mode, or color Doppler and PW Mode

Note 3: Breast, Testes, Thyroid, Penis

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

510(k) Summary

Sponsor:

Siemens Medical Solutions, Inc.
Ultrasound Division
5168 Campus Drive
Plymouth Meeting, PA 19462

Contact Person:

Primary Contact:

Kevin Kong, RAC

Telephone: (650) 969-9112

Secondary Contact:

Lawrence Engle

Telephone: (610) 834-1220 Ext 102

Submission Date: July 8, 2016

Device Name: ACUSON Freestyle™ Ultrasound System

Common Name: Diagnostic Ultrasound System

Classification:

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

Diagnostic Ultrasound Transducer

- 21 CFR # 892.1570
- Product Code ITX

Legally Marketed Predicate Devices

The ACUSON Freestyle™ Ultrasound System in this 510k is a modification to Penrith Elettra Diagnostic Ultrasound System (Primary predicate), previously cleared in K100598. The secondary predicate device is the ACUSON S2000 as cleared on K152369.

Device Description:

The ACUSON Freestyle™ Ultrasound System is an ultrasound imaging system, which operates with linear, curvilinear, array transducers. The transducers may be used in either a wireless or wired configuration through a cable connected to the system.

Intended Use

The ACUSON Freestyle™ Ultrasound System is intended for diagnostic imaging or fluid flow analysis of the human body including: Fetal, Abdominal, Intraoperative, Intraoperative Neurological, Pediatric, Small Organ, Neonatal Cephalic, Cardiac, Peripheral Vessel, Musculoskeletal (Conventional), Musculoskeletal Superficial.

Substantial Equivalence

The submission device is a modification to Elettra Ultrasound System previously cleared in K100598 with regard to both intended use and technological characteristics and is also substantially equivalent to the ACUSON S2000 as cleared in K152369.

Freestyle™ Ultrasound System Substantial Equivalence Table

Description	ACUSON S2000 (Predicate K152369)	Penrith Elettra (Predicate K100598)	ACUSON Freestyle™ (This submission)
Indications for Use (Clinical Applications)	The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications. The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the “ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force,	Diagnostic Imaging or fluid flow analysis of the human body as follows: Fetal, Abdominal, Intraoperative Intraoperative Neurological, Pediatric, Small Organ, Neonatal Cephalic, Cardiac, Peripheral Vessel, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial)	Same as K100598

Description	ACUSON S2000 (Predicate K152369)	Penrith Elettra (Predicate K100598)	ACUSON Freestyle™ (This submission)
	Endorsed by the Society for Vascular Imaging". The ACUSON Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.		
Product Code(s)	System: IYO, IYN Transducer: ITX Catheter: OBJ	-System: IYO, IYN -Transducers: ITX	-System: IYO, IYN -Transducers: ITX
Transducer Types	-Linear Array -Phased Array -Curved Array -Pencil -TEE	-Linear Array -Curvilinear Array	-Linear Array -Curvilinear Array

Description	ACUSON S2000 (Predicate K152369)	Penrith Elettra (Predicate K100598)	ACUSON Freestyle™ (This submission)
Modes of Operation	-B Mode -M Mode -Pulsed Wave Doppler (PWD) -Continuous Wave Doppler (CWD) -Color Doppler -Amplitude Doppler -Combined (BMDC)	-B Mode -Color Doppler Mode -Amplitude Doppler Mode	-B Mode -Color Doppler Mode -Amplitude Doppler Mode
Functionality with Siemens ARTIS System	N/A	N/A	√
Imaging			
Multi-Hertz multiple frequency imaging	√	√	√
Acoustic output display standard compliance	√	√	√
Measurements (Distance, Area, Elliptical)	√	√	√
Trapezoidal (Wide) Imaging	√	N/A	√

Description	ACUSON S2000 (Predicate K152369)	Penrith Elettra (Predicate K100598)	ACUSON Freestyle™ (This submission)
Wireless Transducer			
Wireless Ultrasound Image Transmission	N/A	B, Color, Amplitude	B, Color, Amplitude
Meets FCC Part 15 Subpart B: Unintentional Radiators	N/A	Yes	Yes
Meets FCC Part 15 Subpart C: Intentional Radiators	N/A	Yes	Yes
Meets FCC Part 15 Subpart F : Ultra Wideband Operation	N/A	Yes	Yes
Meets FCC Part 95 (WMTS)	N/A	No	No
Frequency Range RF Transmitter	N/A	7.5-8.5 GHz	7.5-8.5 GHz
Lithium Ion Battery Operation	N/A	Yes	Yes
Connectivity			
Wireless Network Connectivity	N/A	√	√
External Antenna	N/A	N/A	√
DICOM Compatibility	√	√	√

Non-clinical Tests submitted, referenced, or relied on for determination of substantial equivalence

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

- AAMI/ANSI 60601-1: Medical Electrical Equipment – Part 1 General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2: Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance: Electromagnetic Compatibility
- IEC 60601-2-37: Medical Electrical Equipment – Part 2-37 For Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic Monitoring Equipment
- IEC 62366: Medical Devices – Application of Usability
- IEC 62304: Medical Device Software – Software Life Cycle Process
- NEMA UD-2: Acoustic Output Measurement Standard for Diagnostic Ultrasound
- NEMA UD-3: Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO 10993-1: Biological Evaluation of Medical Devices

Summary discussion of the clinical tests submitted, referenced, or relied on for determination of substantial equivalence

The ACUSON Freestyle™ Ultrasound System is a class II device, and uses the same technology and operating principle as the predicate devices; clinical data is not required for substantial equivalence.

Conclusion

As shown by the substantial equivalence table above, the ACUSON Freestyle™ Ultrasound System is substantially equivalent as the predicate devices; Penrith Elettra Ultrasound System (K100598) and the ACUSON S2000 (K152369).