Siemens Medical Solutions USA, Inc.
% Prithul Bom
Responsible Third-Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

May 26, 2020

Re: K201130
Trade/Device Name: ACUSON Juniper Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, OIJ
Dated: April 27, 2020
Received: April 28, 2020

Dear Prithul Bom:

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/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,

For

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)*

K201130

Device Name
ACUSON Juniper Diagnostic Ultrasound System

Indications for Use *(Describe)*

The ACUSON Juniper ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Abdominal, Obstetrics, Gynecology, Small Parts, Pediatric, Neonatal, Vascular, Urology, Echocardiography, Musculoskeletal, and Intraoperative applications using different ultrasound transducers for different applications. The system also provides the ability to measure anatomical structures and provides analysis packages that provide information used by a physician for clinical diagnostic purposes.

Ultrasound is used as an imaging aid, but may have further restrictions specific to in vitro fertilization (IVF), chorionic villus sampling (CVS), and percutaneous umbilical cord blood sampling (PUBS) procedures. Observe local laws and regulations.

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 can 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 Society of Echocardiography Carotid Intima-Media Thickness Task Force. Endorsed by the Society for Vascular Medicine."

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.

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **ACUSON Juniper™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)	P	P	P		P	P	BCDM	
Obstetrics (Note 2)	P	P	P		P	P	BCDM	
Gynecology (Note 3)	P	P	P		P	P	BCDM	
Small Parts (Note 4)	P	P	P		P	P	BCDM	
Pediatric (Note 5)	P	P	P	P	P	P	BCDM	
Neonatal (Note 6)	P	P	P	P	P	P	BCDM	
Vascular (Note 7)	P	P	P	P	P	P	BCDM	
Urology (Note 8)	P	P	P		P	P	BCDM	
Echocardiography (Note 9)	P	P	P	P	P	P	BCDM	
Musculoskeletal (Note 10)	P	P	P		P	P	BCDM	
Intraoperative (Note 11)	P	P	P		P	P	BCDM	

N = new indication; P = previously cleared by K180039

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography, Trans-esophageal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

(Intraoperative Abdomen)

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

_____
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

_____
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k)_____

510(k) Summary
K201130

Date: May 7, 2020

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

Contact Person:
HyunJung Lee
Tel: (425) 281-5061

2. Device Name: ACUSON Juniper 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
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Biopsy Needle Guide Kit	892.1560	90-OIJ

Manufacturing Site:
Siemens Healthineers Ltd.
2nd -3rd floor, 143, Sunhwan-ro,
Jungwon-gu, Seongnam-si, Gyeonggi-do,
Republic of Korea

3. Legally Marketed Predicate Devices

The ACUSON Juniper Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the company's own products, ACUSON Juniper(K180039) which is primary predicate device, and ACUSON P200(K191922), ACUSON X700 (K141846) and ACUSON Sequoia (K193257) as reference device.

The additional predicates are the indications for Trans-esophageal Echocardiography and 13L4, 5VT transducers and Needle guide for 13L4 and SW applications of VVI and LVO described in section 6 Summary of Technological Characteristics.

4. Device Description

The ACUSON Juniper Diagnostic Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound systems with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M mode, Doppler Tissue Image, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

The 13L4 needle guide kit is newly introduced on this submission.

5. Intended Use/Indications for Use

The ACUSON Juniper ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Abdominal, Obstetrics, Gynecology, Small Parts, Pediatric, Neonatal, Vascular, Urology, Echocardiography, Musculoskeletal, and Intraoperative applications using different ultrasound transducers for different applications.

The system also provides the ability to measure anatomical structures and provides analysis packages that provide information used by a physician for clinical diagnostic purposes.

Ultrasound is used as an imaging aid, but may have further restrictions specific to in vitro fertilization (IVF), chorionic villus sampling (CVS), and percutaneous umbilical cord blood sampling (PUBS) procedures. Observe local laws and regulations

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 can 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 Society of Echocardiography Carotid Intima-Media Thickness Task Force. Endorsed by the Society for Vascular Medicine."

6. Summary of Technological Characteristics

The modified ACUSON Juniper Ultrasound System is the same as the company's own previously cleared ACUSON Juniper (K180039), ACUSON X700 (K141846), ACUSON P200 (K191922) and the ACUSON Sequoia (K193257) with regard to both intended use and technological characteristics. Both the modified ultrasound system under this review and the predicate ultrasound systems function in the same manner as all diagnostic ultrasound systems and transducers.

The foundation of the ACUSON Juniper (this submission) is the ACUSON Juniper (K180039) with features and transducers integrated with the ACUSON Juniper (K180039) hardware and the ACUSON Juniper (this submission) reuse software developed for ACUSON Juniper (K180039) mainly as well as the SW applications of VVI and LVO from ACUSON X700 (K141846) and V5Ms from ACUSON P200(K191922).

	ACUSON Juniper This submission	**ACUSON Juniper (K180039) Predicate Device**	**ACUSON X700 (K141846) Reference Device**
Indications for Use:			
▪ Abdominal (Abdominal, Renal, Bowel,	√	√	

	ACUSON Juniper **This submission**	**ACUSON Juniper** **(K180039)** **Predicate Device**	**ACUSON X700** **(K141846)** **Reference Device**
Focused Assessment with Sonography for Trauma, Lung)			
▪ Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)	√	√	
▪ Gynecology (Gynecology, Pelvic Floor)	√	√	
▪ Small Parts (Breast, Testicles, Penile, Thyroid)	√	√	
▪ Pediatric (Pediatric Hip Joint, Pediatric Abdomen)	√	√	
▪ Neonatal (Neonatal Head)	√	√	
▪ Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)	√	√	
▪ Urology (Pelvis, Prostate)	√	√	
▪ Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography, Trans-esophageal Echocardiography)	√	√ (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)	√ (Trans-esophageal Echocardiography)
▪ Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)	√	√	
▪ Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)	√	√	
Modes:			
▪ 2D (Brightness mode)	√	√	
▪ C (Color Flow Doppler)	√	√	
▪ D (Doppler)	√	√	
▪ M (Motion Mode)	√	√	
▪ CW (Continuous Waver Doppler)	√	√	
Features:			

	ACUSON Juniper **This submission**	**ACUSON Juniper** **(K180039)** **Predicate Device**	**ACUSON X700** **(K141846)** **Reference Device**
▪ DICOM (3.0 Connectivity, Worklist, MPPS)	√	√	
▪ DICOM SR OB/GYN	√	√	
▪ DICOM SR Cardiac	√	√	
▪ DICOM SR Vascular	√	√	
▪ syngo Arterial Health Package (AHP)	√	√	
▪ syngo Auto Follicle	√	√	
▪ syngo Auto OB	√	√	
▪ eSie Left Heart (eSie LH)	√	√	
▪ Stress Echo	√	√	
▪ 3-Scape Imaging	√	√	
▪ fourSight 4D	√	√	
▪ Advanced fourSight 4D Imaging	√	√	
▪ eSie Touch Elasticity Imaging	√	√	
▪ eSie Measure Workflow Acceleration Package	√	√	
▪ eSieScan Workflow Protocol	√	√	
▪ Virtual Touch Quantification (VTQ)	√	√	
▪ SieScape Panoramic Imaging	√	√	
▪ Dynamic Tissue Contrast Enhancement (DTCE)	√	√	
▪ Advanced SieClear (ASC)	√	√	
▪ Clarify Vascular Enhancement (Clarify VE)	√	√	
▪ eSieImage (TEQ/TGO)	√	√	
▪ Anatomical M-mode (AMM)	√	√	
▪ HD Zoom (Res)	√	√	
▪ Needle Visualization	√	√	
▪ Tissue Harmonic Imaging (THI)	√	√	

	ACUSON Juniper This submission	**ACUSON Juniper (K180039) Predicate Device**	**ACUSON X700 (K141846) Reference Device**
▪ Doppler Tissue Imaging (DTI)	√	√	
▪ Custom Tissue Imaging (CTI)	√	√	
▪ eSieCalcs	√	√	
▪ Wireless	√	√	
▪ Veterinary(VET) Imaging	√	√	
▪ US Security (Virus Protection)	√	√	
▪ VVI(Velocity Vector Image)	√	-	√
▪ LVO(Left Ventricular Opacification)	√	-	√

7. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence

The device has 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 to applicable medical device safety standards. The systems comply with the following voluntary standards:

- IEC 62359:2010 /A1(2017), Ultrasonic – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic field / This document and its separate amendments continue to be valid together with the consolidation version.
- Safety and EMC Requirements for Medical Equipment
  - 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)
  - IEC 60601-1:2005/A1(2012), Medical electric equipment – Part 1: General requirements for basic safety and essential performance / This document and its separate amendments continue to be valid together with the consolidated version
  - 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
  - IEC 60601-2-18 Edition 3.0 2009-08, Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
  - 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

- ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

8. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

Since the ACUSON Juniper Diagnostic Ultrasound System uses the same technology and principles as existing devices, clinical data is not required to support substantial equivalence.

9. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms to 21 CFR 820 Quality System Regulation and ISO 13485:2016 quality system standards. The product is designed to conform to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound system has accumulated a long history of safe and effective performance. Therefore, it is the opinion of Siemens Medical Solutions USA, Inc. that the ACUSON Juniper Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.