August 16, 2022

Siemens Medical Solutions USA, Inc.
% Sulgue Choi
Regulatory Affairs
22010 South East 51st Street
ISSAQUAH WA 98029

Re: K221190
Trade/Device Name: ACUSON Juniper Diagnostic Ultrasound System and ACUSON Juniper Select Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, OIJ
Dated: July 21, 2022
Received: July 22, 2022

Dear Sulgue Choi:

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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221190

Device Name
ACUSON Juniper Diagnostic Ultrasound System,
ACUSON Juniper Select Diagnostic Ultrasound System

Indications for Use *(Describe)*

For ACUSON Juniper

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.

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.

For ACUSON Juniper Select

The ACUSON Juniper Select 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, Vascular, Urology, Echocardiography and Musculoskeletal 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.

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.

Operating Modes
2D-Mode
• 2D-Mode with Harmonic Imaging
Color flow Doppler
• Color (Velocity)
• Power (Energy)
Pulsed Wave Doppler
• Pulsed Wave Doppler Tissue Imaging
• High Pulsed Repetition Frequency Pulsed Wave Doppler
Continuous Wave Doppler
• Steerable Continuous Wave Doppler for imaging transducers
• Auxiliary Continuous Wave Doppler for pencil transducers
M Mode
• M-Mode with Harmonic Imaging
• Anatomical M-mode
3D/4D Volume Imaging

Combined Modes
• 2D-Mode with Color
• 2D-Mode with Doppler
• 2D-Mode with Color and Doppler
• 2D-Mode with M-Mode
• 2D-Mode with M-Mode and Color
• 2D-Mode with Elastography*
• 2D-Mode with Contrast Agent Imaging
• 2D/Anatomical M-mode
*Available only for the ACUSON Juniper system.

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
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."

510(k) Summary K221190

Date: Jul 12, 2022

1. Sponsor:
Siemens Medical Solutions USA, Inc.,
Ultrasound Division
22010 South East 51st Street
Issaquah, WA 98029

Contact Person:
Sulgue Choi
Tel: (425) 281-9898

Secondary Contact Person:
Bongsoo Cho
Tel: +82 10 4697 2268
E-mail: bongsoo.cho@siemens-healthineers.com

2. Device Name:
ACUSON Juniper Diagnostic Ultrasound System
ACUSON Juniper Select 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 and ACUSON Juniper Select Diagnostic Ultrasound System are the multi-purpose diagnostic ultrasound systems with accessories and proprietary software and is substantially equivalent to the company's own products.

- Primary Predicate Device: ACUSON Juniper(K201130)
- Reference Device: ACUSON Redwood(K210743)

4. Device Description

The ACUSON Juniper Diagnostic Ultrasound System and ACUSON Juniper Select Diagnostic Ultrasound System are the multi-purpose mobile, software controlled, diagnostic ultrasound systems with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Their 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.

5. Intended Use/Indications for Use

For ACUSON Juniper

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.

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.

For ACUSON Juniper Select

The ACUSON Juniper Select 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, Vascular, Urology, Echocardiography and Musculoskeletal 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.

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.

Operating Modes

2D-Mode
- 2D-Mode with Harmonic Imaging

Color flow Doppler
- Color (Velocity)
- Power (Energy)

Pulsed Wave Doppler
- Pulsed Wave Doppler Tissue Imaging

- High Pulsed Repetition Frequency Pulsed Wave Doppler

Continuous Wave Doppler

- Steerable Continuous Wave Doppler for imaging transducers
- Auxiliary Continuous Wave Doppler for pencil transducers

M Mode

- M-Mode with Harmonic Imaging
- Anatomical M-mode

3D/4D Volume Imaging

Combined Modes

- 2D-Mode with Color
- 2D-Mode with Doppler
- 2D-Mode with Color and Doppler
- 2D-Mode with M-Mode
- 2D-Mode with M-Mode and Color
- 2D-Mode with Elastography*
- 2D-Mode with Contrast Agent Imaging
- 2D/Anatomical M-mode

*Available only for the ACUSON Juniper system.

6. Summary of Technological Characteristics and Determination of Substantial Equivalence

The ACUSON Juniper Diagnostic Ultrasound System and ACUSON Juniper Select Diagnostic Ultrasound System are substantially equivalent to the company's own products that are already cleared for US distribution. The predicate devices of ACUSON Juniper & ACUSON Juniper Select are ACUSON Juniper (K201130) and ACUSON Redwood (K210743) with regards to intended use, indications for use, technological characteristics (Transducers, accessories and software features) and safety and effectiveness.

The submission device differs from the predicated devices as following:

1) ACUSON Juniper:
   (1) Transducer & Accessories
   - The addition of the 6C1, which is substantially equivalent to the 5C1 transducer previously cleared on the submission device, ACUSON Juniper (K201130).
   - The addition of the 14L4, which is substantially equivalent to the 13L4 transducer previously cleared on the ACUSON Juniper (K201130).
   - The addition of the CW8, which is substantially equivalent to the CW5 transducer previously cleared on the ACUSON Juniper (K201130).
   - The addition of needle guide kit, 14L4, which is substantially equivalent to the needle guide Kit, 13L4 previously cleared on the ACUSON Juniper (K201130).
   - Addition of a battery pack and BW printer

   (2) Software Feature:
   - The addition of 'Contrast Agent Imaging' clinical application, which was already cleared on the ACUSON Redwood(K210743)).

2) ACUSON Juniper Select: The proposed ACUSON Juniper Select systems is substantially equivalent to ACUSON Juniper (K201130) with regards to intended use, Indications for use, technological characteristics (Transducers, accessories and

software features) and safety and effectiveness. All of technological characteristics are migrated (identical SW & HW platform) from the predicate device, ACUSON Juniper (K201130), and there is no new feature or transducer compared to the predicate.

The ACUSON Juniper and ACUSON Juniper Select are substantially equivalent to the predicate devices with regard to the intended use, indications for use and technical characteristics.

	ACUSON Juniper **This submission**	**ACUSON Juniper Select** **This submission**	**ACUSON Juniper (K201130)** **Predicate device**	**ACUSON Redwood (K210743)** **Reference device**
Indications for Use:				
▪ Abdominal (Abdominal, Abdominal Difficult, Renal, Bowel, 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)	√	√	√	
▪ Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)	√	√	√	

	ACUSON Juniper **This submission**	**ACUSON Juniper Select** **This submission**	**ACUSON Juniper (K201130)** **Predicate device**	**ACUSON Redwood (K210743)** **Reference device**
▪ Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)	√		√	
Modes:				
▪ 2D (Brightness mode)	√	√	√	
▪ C (Color Flow Doppler)	√	√	√	
▪ D (Doppler)	√	√	√	
▪ M (Motion Mode)	√	√	√	
▪ CW (Continuous Waver Doppler)	√	√	√	
Features:				
▪ 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	√	√	√	

	ACUSON Juniper This submission	ACUSON Juniper Select This submission	ACUSON Juniper (K201130) Predicate device	ACUSON Redwood (K210743) Reference device
(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)	√	√	√	
▪ 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)	√	√	√	
▪ Contrast Agent Imaging	√		-	√

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

The subject of this premarket submission, ACUSON Juniper and ACUSON Juniper Select, did not require clinical studies to support substantial equivalence.

9. Summary

Subject devices and predicate devices have the same intended use and substantially equivalent key technological features, and the non-clinical data support the safety of the device and demonstrate that the ACUSON Juniper and ACUSON Juniper Select should perform as intended in the specified use conditions. Therefore, it is the opinion of Siemens Medical Solutions USA, Inc. that the ACUSON Juniper and ACUSON Juniper Select to be as safe, as effective, and performance is substantially equivalent to the predicate devices.