November 13, 2025

Siemens Medical Solutions USA, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K253457
Trade/Device Name: ACUSON Juniper Diagnostic Ultrasound System;
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: October 6, 2025
Received: October 6, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253457 ?

Please provide the device trade name(s). ?

ACUSON Juniper Diagnostic Ultrasound System;
ACUSON Juniper Select Diagnostic Ultrasound System

Please provide your Indications for Use below. ?

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 supports the Ultrasound-Derived Fat Fraction (UDFF) measurement tool to report an index that can be useful as an aid to a physician managing adult patients with hepatic steatosis.
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 the state of their cardiovascular system.

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 the state of their cardiovascular system.

Operating Modes

2D-mode
– 2D-mode with Harmonic imaging
– 2D-mode with Simultaneous imaging for biplane transducers*

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 phased array 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-mode with Anatomical M-mode

*Available only on the ACUSON Juniper system.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) Summary

K253457

Date: Sept 25, 2025

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

Primary Contact: DongJun Kim
Regulatory Affairs Specialist
+82 10-4697-2661

Secondary Contact : Shilpa Rapaka
Regulatory Affairs Manager
+1 512-913-1053

2. Device Name: ACUSON Juniper Diagnostic Ultrasound System
ACUSON Juniper Select Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System

Classification: Regulatory Class: II
Classification Panel: Radiology

Classification Name	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX
Biopsy Needle Guide Kit	892.1560	OIJ

Manufacturing Site: Siemens Healthcare s.r.o.
Panattoni Park Kosice Airport ul., Andreja
Kvasa 5 040 17, Kosice-Barca, Slovakia

3. Legally Marketed Predicate and Reference Device

The ACUSON Juniper Diagnostic Ultrasound System and ACUSON Juniper Select Diagnostic Ultrasound System are multi-purpose diagnostic ultrasound systems with proprietary software and optional accessories and are substantially equivalent to the company's own Ultrasound devices.

Predicate device: ACUSON Juniper diagnostic ultrasound system and ACUSON Juniper Select Diagnostic Ultrasound System (K230207)

Reference devices: ACUSON Sequoia Diagnostic Ultrasound System (K251481) and ACUSON NX3 Elite Diagnostic Ultrasound System (K192835)

4. Device Description

The ACUSON Juniper Diagnostic Ultrasound System and ACUSON Juniper Select Diagnostic Ultrasound System are 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 mode, Amplitude Doppler Mode, combination modes, Harmonic Imaging and 3D Imaging modes, or Harmonic Imaging and 4D imaging modes on a flat panel display for diagnostic ultrasound imaging.

5. Indications for Use

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 supports the Ultrasound-Derived Fat Fraction (UDFF) measurement tool to report an index that can be useful as an aid to a physician managing adult patients with hepatic steatosis.

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 the state of their cardiovascular system.

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 the state of their cardiovascular system.

Operating Modes

- 2D-mode
  - 2D-mode with Harmonics Imaging
  - 2D-mode with Simultaneous imaging for biplane transducers*
- 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 phased array transducers
  - Auxiliary Continuous Wave Doppler for pencil transducers
- M-mode
  - M-mode with Harmonics 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-mode with Anatomical M-mode

*Available only on the ACUSON Juniper system

6. Substantial Equivalence and Comparison of Technological Comparison to Predicate and Reference Devices

The purpose of this Traditional 510(k) is to introduce the following changes compared to the predicate device:

- Software features and workflow improvements:
    - The addition of Virtual Touch UDFF (Ultrasound-Derived Fat Fraction) feature, which is substantially equivalent to Virtual Touch UDFF feature previously cleared on the ACUSON Sequoia (K251481).
    - The addition of Auto IMT feature, which is substantially equivalent to Auto IMT feature previously cleared on the ACUSON Sequoia (K251481).

- New 10BCC3 transducer and needle guide:
    - The addition of 10BCC3 transducer, which is substantially equivalent to BP10-3 transducer previously cleared on the ACUSON NX3 Elite (K192835).
    - The addition of needle guides for 10BCC3 transducer which is substantially equivalent to needle guides for BP10-3 transducer previously cleared on the ACUSON NX3 Elite (K192835).

The intended use, indications for use, use environment, technological characteristics, acoustic output, software features, hardware, compatible transducers, safety, and effectiveness of the subject devices are substantially equivalent to the predicate and/or reference devices.

7. Nonclinical Data

The ACUSON Juniper and Juniper Select Diagnostic Ultrasound Systems comply with the following standards and guidance documents:

- IEC 62359: Edition 2.1 2017-09, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields / Combines IEC 62359 (2010-10) and AMD 1 (2017-09)
- ANSI/AAMI ES60601-1:2005/A2:2021: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A1(2012)/A2(2020))
- IEC 60601-1:2005/A1(2012)/A2(2020), 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 4.1 2020-09, 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 3.0 2024, 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
- IEC 60601-1-6:2010+A1:2013+A2:2020 Medical Electrical Equipment Part 1-6, General Requirements for Basic Safety and Essential Performance- Collateral standard: Usability
- ANSI AAMI ISO 14971: Medical devices- Applications of risk management to medical devices, 2019
- IEC 62304: Medical Device Software – Software life cycle process, 2006 + A 2015
- ISO 13485:2016 Medical devices – Quality management systems- Requirements for regulatory purposes
- FDA Ultrasound Guidance document, “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers,” issued in February 2023

Non-Clinical verification testing has been performed addressing system level requirements according to system and design specifications, and risk control measures. Design Control activities to assure the safety and effectiveness of the subject devices include but are not limited to the following:

- Requirements Review

- Risk Analysis and Risk Management
- Product Specifications
- Design Reviews
- Safety Testing
- Verification and Validation

8. Clinical Data

Summary of Clinical Tests

Since the ACUSON Juniper and Juniper Select Diagnostic Ultrasound Systems use the same technology and principles as existing predicate devices, clinical studies were not required to support substantial equivalence.

UDFF Study Summary

Ultrasound-Derived Fat Fraction (UDFF) is a software tool that measures tissue in a selected region of interest and reports an index for assessing fat content in the liver. UDFF can be useful as an aid to a physician managing adult patients with hepatic steatosis.

The 6C1 transducer on the Condor (software platform) is compatible with the UDFF option. The UDFF feature on the Condor platform (functionality, algorithms for UDFF measurements and calculations, implementation, etc.) is identical (remains unchanged) when compared to the UDFF feature in the reference device.

Two different studies were conducted to evaluate the performance of the UDFF feature on the Condor. The demographic distribution of the study population in the two different studies are presented in the following table:

Study 1	Study 2
N= 31 subjects **Ethnicity/Country** USA = 15 Korea = 16	N= 31 subjects **Ethnicity/Country** USA = 31

Sex Male = 24 Female = 7 **Age (years)** Mean ±SD = 41.4 ± 8.5 Range = 24 – 63 **BMI (kg/m2)** Mean ± SD = 27.5 ± 7.1 Range = 16.7 – 55.2	**Sex** Male = 11 Female = 20 **Age (years)** Mean ±SD = 52.2 ± 10.1 Range = 31 – 75 **BMI (kg/m2)** Mean ± SD = 31.9 ± 8.2 Range = 20.5 – 56

The study details and results are presented in the following table:

Study No.	Study Objective	Evaluation Criteria	Results
1	To verify the correlation between the performance of the UDFF feature on Condor - ACUSON Juniper and Maple (Juniper is the subject device) and the UDFF feature on ACUSON Sequoia (reference device)	Significance level p-Value < 0.05 in a two-tailed test	Pearson Correlation coefficient between UDFF on Condor and ACUSON Sequoia was 0.97, and the difference is not statistically significant (p=0.459 and t-statistic = -0.750)
	To verify the clinical reliability of the UDFF feature on the Condor	Test-retest ICC greater than 0.75	ICC = 0.97. The reliability of the UDFF feature on Condor is considered excellent.
2	To verify that UDFF of Condor shows good agreement with MRI-PDFF	Absolute mean difference less than 5 percentage points and Bland-Altman limits of agreement within ±15 percentage points	Condor UDFF and MRI's PDFF had Bland-Altman limits of agreement between -4.16 to 10.05 percentage points with a mean absolute difference of 2.95 percentage points.
	To verify the clinical accuracy of the Condor UDFF feature	AUROC greater than 0.80	Performance of UDFF on Condor showed strong performance with AUROC 0.85

9. Summary

The subject and predicate devices are substantially equivalent in terms of intended use, indications for use, use environment, technological characteristics, acoustic output, software features, hardware, compatible transducers, safety, and effectiveness. For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed subject devices continue to meet their intended use, and the modifications made do not raise new or different questions of safety and effectiveness in support of a substantially equivalence determination.