September 26, 2023

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

Re: K232617
Trade/Device Name: ACUSON Maple Diagnostic Ultrasound System
ACUSON Maple 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: August 28, 2023
Received: August 28, 2023

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,

Marjan Nabili -S for

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
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)*

K232617

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

Indications for Use *(Describe)*

For ACUSON Maple Diagnostic Ultrasound System

The ACUSON Maple 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, 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.

For ACUSON Maple Select Diagnostic Ultrasound System

The ACUSON Maple 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
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/Anatomical M-mode

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.

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510(k) Summary

K232617

Date: July 05, 2023

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

Contact Person:
Shilpa Rapaka
Phone: 512-913-1053

Secondary Contact:
JungIn Choi
Phone: +82 10 4695 8694

2. Device Name(s):
ACUSON Maple Diagnostic Ultrasound System
ACUSON Maple Select Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:
Regulatory Class: Class 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 Healthcare s.r.o
Panattoni Park Kosice Airport ul.
Andreja Kvasa 5040 17, Kosice-Barca, Slovakia

3. Legally Marketed Predicate Devices

The ACUSON Maple Diagnostic Ultrasound System and ACUSON Maple 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.

- Primary Predicate Device: ACUSON Juniper and Juniper Select (K230207)
- Reference Devices: ACUSON NX2 and NX2 Elite (K173981), ACUSON SC2000 (K211726)

4. Device Description

The ACUSON Maple Diagnostic Ultrasound System and ACUSON Maple 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. Intended Use/Indications for Use

ACUSON Maple

The ACUSON Maple Ultrasound Diagnostic Ultrasound 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, 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.

ACUSON Maple Select

The ACUSON Maple Select Diagnostic Ultrasound 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
- 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/Anatomical M-mode

6. Substantially Equivalent Devices and Summary of Technological Characteristics

The ACUSON Maple Diagnostic Ultrasound System and ACUSON Maple Select Diagnostic Ultrasound System are substantially equivalent to the company's own Ultrasound devices that are already cleared for distribution in the United States. The predicate and reference devices of ACUSON Maple

and ACUSON Maple Select are ACUSON Juniper and Juniper Select (K230207), ACUSON NX2 and NX2 Elite (K173981) and ACUSON SC2000 (K211726) with regards to intended use, indications for use, technological characteristics (transducers, accessories, software features), safety, and effectiveness.

The submission device differs from the predicate/reference devices as follows:

1) ACUSON Maple

- The addition of the C5-2v transducer (new part number) which is substantially equivalent to the C5-2v transducer previously cleared on ACUSON NX2 and ACUSON NX2 Elite (K173981).
- The addition of the 14L4a transducer which is substantially equivalent to the 14L4 transducer previously cleared on ACUSON Juniper and ACUSON Juniper Select (K230207).
- The addition of the 5C1a transducer, which is substantially equivalent to the 5C1 transducer previously cleared on ACUSON Juniper and ACUSON Juniper Select (K230207).
- The addition of needle guide kit 14L4a which is substantially equivalent to the needle guide kit 14L4 previously cleared on ACUSON Juniper and Juniper Select (K230207).
- The addition of needle guide kit 5C1a which is substantially equivalent to the needle guide kit 5C1 previously cleared on ACUSON Juniper and Juniper Select (K230207).
- The addition of needle guide kit C5-2v which is substantially equivalent to the needle guide kit C5-2v previously cleared on ACUSON NX2 and NX2 Elite (K173981).

2) ACUSON Maple Select

- The addition of the C5-2v transducer (new part number) which is substantially equivalent to the C5-2v transducer previously cleared on ACUSON NX2 and ACUSON NX2 Elite (K173981).
- The addition of the 14L4a transducer which is substantially equivalent to the 14L4 transducer previously cleared on ACUSON Juniper and ACUSON Juniper Select (K230207).
- The addition of needle guide kit 14L4a which is substantially equivalent to the needle guide kit 14L4 previously cleared on ACUSON Juniper and Juniper Select (K230207).
- The addition of needle guide kit C5-2v which is substantially equivalent to the needle guide kit C5-2v previously cleared on ACUSON NX2 and NX2 Elite (K173981).

7. Nonclinical Data

The proposed devices have been evaluated for acoustic output, biocompatibility, cleaning, 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.

- AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) and AMD2: 2021 Medical electrical equipment- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, AMD2: 2021)
- IEC 60601-1:2005/A1(2012)/A2(2020) (Ed. 3.2), 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: 2014/A1(2020), 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
- 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

8. Clinical Data

The proposed ACUSON Maple and ACUSON Maple Select did not require any clinical studies to support substantial equivalence.

9. Summary

The subject, predicate, reference devices have same indications for use, technological characteristics (transducers, accessories, software features), safety, and effectiveness. The non-clinical data support the safety of the device and demonstrate that the ACUSON Maple and ACUSON Maple Select perform as intended in the specified use conditions. Therefore, it is the opinion of Siemens Medical Solutions USA, Inc. that the ACUSON Maple and ACUSON Maple Select are as safe and effective with substantially equivalent performance as the predicate/reference devices.