January 31, 2020

Siemens Medical Solutions USA, Inc.
Ultrasound Division
% Sulgue Choi
Regulatory Affairs
685 East Middlefield Road
MOUNTAIN VIEW CA 94043

Re: K193257
Trade/Device Name: ACUSON Sequoia 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
Dated: December 10, 2019
Received: December 12, 2019

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,

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)*
K193257

Device Name
ACUSON Sequoia Diagnostic Ultrasound System

Indications for Use *(Describe)*
The ACUSON Sequoia 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: Fetal, Abdominal, Pediatric, Neonatal Cephalic, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Pelvic, Vascular, Musculoskeletal and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures for fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal 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.

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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# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **ACUSON Sequoia Diagnostic Ultrasound System**

Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | BMDC | |
| Abdominal | | P | P | P | | P | P | | BMDC | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMDC | |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | |
| Neonatal Cephalic | | N | N | N | | N | N | | BMDC | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | BMDC | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | P | P | P | | P | P | | BMDC | |
| Transvaginal | | P | P | P | | P | P | | BMDC | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMDC | |
| Musculo-skeletal Superficial | | P | P | P | | P | P | | BMDC | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **4V1 Phased Array Transducer**

Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | BMDC | |
| Abdominal | | P | P | P | | P | P | | BMDC | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMDC | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **DAX Curved Array Transducer**
Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | BMCD | |
| Abdominal | | P | P | P | | P | P | | BMCD | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMCD | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **5C1 Curved Array Transducer**

Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | BMCD | |
| Abdominal | | P | P | P | | P | P | | BMCD | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMCD | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **9C3 Curved Array Transducer**
Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | BMCD | |
| Abdominal | | P | P | P | | P | P | | BMCD | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMCD | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMCD | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **18L6 Linear Array Transducer**
Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMCD | |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMCD | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMCD | |
| Musculo-skeletal Superficial | | P | P | P | | P | P | | BMCD | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices
510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **14L5 Linear Array Transducer**
Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMCD | |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMCD | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMCD | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMCD | |
| Musculo-skeletal Superficial | | P | P | P | | P | P | | BMCD | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices
510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **10L4 Linear Array Transducer**

Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | BMCD | |
| Abdominal | | P | P | P | | P | P | | BMCD | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMCD | |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMCD | |
| Neonatal Cephalic | | N | N | N | | N | N | | BMCD | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMCD | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMCD | |
| Musculo-skeletal Superficial | | P | P | P | | P | P | | BMCD | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices
510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **9EC4 Endocavity Transducer**
Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | P | P | P | | P | P | | BMCD | |
| Transvaginal | | P | P | P | | P | P | | BMCD | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices
510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **5V1 Phased Array Transducer**
Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMCD | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | BMCD | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **8V3 Phased Array Transducer**

Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | P | P | P | | P | P | | BMCD | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMCD | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | N | N | N | | N | N | | BMCD | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | BMCD | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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510(k)_____

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **CW2 Continuous Wave Transducer**
Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | P | | | | | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | P | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K180067

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **10V4 Phased Array Transducer**
Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | N | N | N | | N | N | | BMCD | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | N | N | N | N | N | N | | BMCD | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | N | N | N | | N | N | | BMCD | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | N | N | N | N | N | N | | BMCD | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K193257

Device Name: **18H6 Linear Array Transducer**
Intended Use: Ultrasound 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) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | N | N | N | | N | N | | BMCD | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | N | N | N | | N | N | | BMCD | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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510(k)_____

**510(k) Summary** **K193257**

**Date:** Jan 29, 2020

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

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

**2. Device Name:** ACUSON Sequoia 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 |

**Manufacturing Site:**
Jabil Inc.
3800 Giddings Road,
Auburn Hills, Michigan, 48326, UNITED STATES

Siemens Medical Solutions USA, Inc.
22010 S.E. 51st Street,
Issaquah, WA, 98029, UNITED STATES

**3. Legally Marketed Predicate Devices**

The ACUSON Sequoia 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, the ACUSON X800 (K180067) which is primary predicated device and the ACUSON S family (K172162).

The additional predicates are the indications for Neonatal Cephalic and 18H6, 10V4 transducers which are cleared under ACUSON S family (K172162) as described in the table of section 6 Summary of Technological Characteristics.

## 4. Device Description

The ACUSON Sequoia Diagnostic Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display of thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to transmit and receive 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 Mode, Amplitude Doppler Mode, a combination of modes and Harmonic Imaging on a Display.

## 5. Intended Use

The ACUSON Sequoia 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: Fetal, Abdominal, Pediatric, Neonatal Cephalic, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Pelvic, Vascular, Musculoskeletal and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures for fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal 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.

## 6. Summary of Technological Characteristics

The modified ACUSON Sequoia Ultrasound System is the same as the company's own previously cleared ACUSON X800 (K180067) and the ACUSON S family (K172162) 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 submission device differs from the predicated devices as following:

- The modified ACUSON Sequoia Ultrasound System includes the addition of the 18H6 transducer. The 18H6 transducer is similar to the 14L5 SP in its indications for use, however is technologically different due to the number of elements (14L5 SP =128 elements and 18H6=192 elements). The 14L5 SP was cleared as a part of the ACUSON S Family under K172162.
- The modified ACUSON Sequoia Ultrasound System includes the addition of the 10V4. This identical transducer has been previously cleared on the ACUSON S family (K172162)
- The modified ACUSON Sequoia Ultrasound System includes the addition of the 'Neonatal cephalic' clinical application. The identical 'Neonatal cephalic' clinical application has been previously cleared on the ACUSON S family (K172162)

All other hardware and software features of the ACUSON Sequoia Diagnostic Ultrasound device remain unchanged. The ACUSON Sequoia system will be updated with the VA11A software version which will support the additional 18H6 and 10V4 transducers and the 'Neonatal cephalic' clinical application.

The ACUSON Sequoia with software version VA11A is substantially equivalent to the predicate devices with regard to both the intended use, indications for use and technological characteristics. The table below compares the technological characteristics between the submission device and the predicated devices.

| **Feature / Characteristic** | **ACUSON Sequoia This Submission** | **ACUSON X800 K# 180067** | **ACUSON S family S1000/S2000/S3000 K# 172162** |
|---|---|---|---|
| **Indications for Use:** | | | |
| ▪ Fetal | √ | √ | |
| ▪ Abdominal | √ | √ | |
| ▪ Pediatric | √ | √ | |
| ▪ Small Organ | √ | √ | |
| ▪ Cardiac | √ | √ | |
| ▪ Transrectal | √ | √ | |
| ▪ Transvaginal | √ | √ | |
| ▪ Peripheral vessel | √ | √ | |
| ▪ Musculo-skeletal (conventional) | √ | √ | |
| ▪ Musculo-skeletal (superficial) | √ | √ | |
| ▪ Neonatal cephalic | √ | - | √ |
| **Frequencies Supported:** | √ (1.0MHZ~18MHz) | √ (1.0MHZ~18MHz) | √ (2.0MHz~17MHz) |
| **Modes:** | | | |
| ▪ B | √ | √ | |
| ▪ M | √ | √ | |
| ▪ PWD (Pulsed Wave Doppler) | √ | √ | |
| ▪ CWD (Continuous Wave Doppler) | √ | √ | |
| ▪ PW DTI (Doppler Tissue Image) | √ | √ | |
| ▪ Color Doppler | √ | √ | |
| ▪ Power Doppler | √ | √ | |
| ▪ Combined (BMDC) | √ | √ | |
| **Features:** | | | |
| ▪ Harmonic imaging | √ | √ | |
| ▪ Panoramic imaging | √ | √ | |
| ▪ Color Panoramic imaging | √ | √ | |
| ▪ Auto TEQ | √ | √ | |
| ▪ Cardiac Imaging physiological signal display | √ | √ | |
| ▪ eSie OB | √ | √ | |
| ▪ Compounding | √ | √ | |
| ▪ Contrast imaging | √ | √ | |
| ▪ Clarify | √ | √ | |
| ▪ Virtual Touch - Strain | √ | √ | |

| Feature / Characteristic | ACUSON Sequoia This Submission | ACUSON X800 K# 180067 | ACUSON S family S1000/S2000/S3000 K# 172162 |
|---|---|---|---|
| ▪ syngo ® Velocity Vector Imaging | √ | √ | |
| ▪ eSie Calc | √ | √ | |
| ▪ Speed of Sound | √ | √ | |
| ▪ Fusion | √ | √ | |
| ▪ Virtual Touch – pSWE | √ | √ | |
| ▪ Virtual Touch – SWE | √ | √ | |
| ▪ UltraArt | √ | √ | |
| ▪ Modality Compare | √ | √ | |
| ▪ HD Zoom | √ | √ | |
| ▪ Protocols | √ | √ | |
| ▪ InFocus | √ | √ | |
| ▪ Flash sequencing | √ | √ | |
| ▪ Gesture control | √ | √ | |
| ▪ TeamViewer | √ | √ | |
| ▪ Motion Stabilized Persistence | √ | √ | |
| ▪ DICOM | √ | √ | |
| ▪ DICOM SR | √ | √ | |
| **Wireless** | √ | √ | |
| **Monitor: 21" FPD (OLED)** | √ | √ | |
| **Touch Screen: 15" adjustable Touch Screen** | √ | √ | |
| **Output Display Standard (Track 3)** | √ | √ | |
| **Patient Contact Materials** | Tested to ISO 10993-1 | Tested to ISO 10993-1 | |
| **UL 60601-1 Certified** | √ | √ | |
| **Indications for Use** | √ | √ | |

**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, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields / This document and its separate amendments continue to be valid together with the consolidated 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, Medical electrical 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 Fourth edition 2009-10-15, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]

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

Since the ACUSON Sequoia Diagnostic Ultrasound System uses the same technology and principles as existing devices, clinical studies were 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 Sequoia system is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.