January 19, 2021

Siemens Medical Solutions USA, Inc.
Hyunjung Lee
Regulatory Technical Specialist
22010 S.E. 51st Street
Issaquah, Washington 98029

Re: K203726
Trade/Device Name: ACUSON AcuNav Volume Intracardiac Echocardiography Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: December 17, 2020
Received: December 21, 2020

Dear Hyunjung Lee:

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 and Part 809); 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,

Mark Fellman
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
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)*
K203726

Device Name
ACUSON AcuNav Volume Intracardiac Echocardiography Catheter

Indications for Use *(Describe)*
The catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.
The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

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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510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21CFR §807.92(c).

SPONSOR'S NAME & ADDRESS

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OFFICIAL CORRESPONDENT

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SUBMISSION DATE

December 17, 2020

TRADE NAME

ACUSON AcuNav Volume Intracardiac Echocardiography Catheter

COMMON NAME

Ultrasound Catheter

CLASSIFICATION NAME/PRODUCT CODE

Diagnostic Intravascular Catheter/ OBJ

CLASSIFICATION

Class II, 21 CFR 870.1200

PREDICATE DEVICE

#K173618, ACUSON AcuNav Volume ICE Catheter

DESCRIPTION OF MODIFIED DEVICE

The ACUSON AcuNav Volume ICE Catheter is a 12.5F catheter with 90 cm of usable length and four-way steering that provides real-time three-dimensional ultrasound images of anatomical structures and devices, in addition to conventional real-time two-dimensional images. The Change Being Effected is the addition of a clarification instruction for the use of the introducer in the catheter device User Manual and Directions for Use.

INDICATIONS FOR USE

The AcuNav Volume ICE catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.
The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

SUBSTANTIAL EQUIVALENCE CONCLUSION

The AcuNav Volume ICE catheter is substantially equivalent to the company's own previously cleared AcuNav Volume ICE catheter (K173618) with regard to both intended use and technological characteristics. The addition of the clarification in the product labeling does not impact the substantial equivalence of the catheter device as currently cleared under K173618. Both the subject catheter and the predicate catheter function in the same manner as all diagnostic ultrasound catheters.

Feature / Characteristic	**AcuNav Volume ICE** *This Submission*	**AcuNav Volume ICE** *K173618*
Indications for Use:		
▪ Cardiac	√	√
▪ Pediatric	√	√
▪ Intra-luminal	√	√
▪ Intra-cardiac	√	√
Patient Contact Materials	ISO 10993-1	ISO 10993-1

A BRIEF DISCUSSION OF NONCLINICAL TESTS SUBMITTED, REFERENCED, OR RELIED ON IN THE 510(K) FOR A DETERMINATION OF SUBSTANTIAL EQUIVALENCE.

The catheter device remains unchanged and has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The device complies with the following voluntary standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-2
- ISO 10993-1, Biocompatibility
- ISO 11135, Sterilization of health-care products - Ethylene oxide
- ISO 11607-1 and ISO 11607-2, Packaging for terminally sterilized medical devices

The cleared patient contact materials and mechanical safety are unchanged due to the change in labeling.

A SUMMARY DISCUSSION OF THE CLINICAL TESTS SUBMITTED, REFERENCED, OR RELIED ON FOR A DETERMINATION OF SUBSTANTIAL EQUIVALENCE.

Because the AcuNav Volume ICE catheter in this submission uses the same technology, patient contact materials and principles as the predicate device, clinical data is not required to establish substantial equivalence.

SUMMARY

Intended use and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 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 has accumulated a long history of safe and effective performance.

The catheter device remains unchanged from previously cleared submission for the predicate device, AcuNav Volume ICE Catheter (K173618). The Change Being Effected is the addition of a warning to clarify the proper use of the introducer used with the catheter device and does not introduce new safety and effectiveness concerns.