DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 9, 2017

Siemens Medical Solutions USA, Inc.
Shelly Pearce
Director, Regulatory Affairs
685 East Middlefield Road
Mountain View, California 94043

Re: K163478
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: January 19, 2017
Received: January 27, 2017

Dear Shelly Pearce:

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. 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.

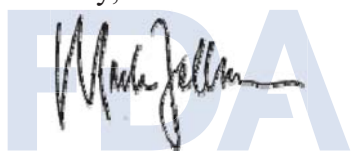
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163478

Device Name
ACUSON AcuNav Volume Intracardiac Echocardiography Catheter

Indications for Use *(Describe)*
The AcuNav Volume is intended for imaging guidance, not treatment delivery, of cardiac interventional percutaneous procedures; intraluminal visualization of great vessel anatomy and physiology; intracardiac visualization of cardiac anatomy, physiology, and devices within the heart of an adult or a pediatric patient.

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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14 510(k) Summary

SPONSOR'S NAME & ADDRESS

Siemens Medical Solutions USA, Inc.
685 East Middlefield Road
Mt. View, CA 94043

OFFICIAL CORRESPONDENT

Shelly Pearce
Director, Regulatory Affairs
Phone: 650-279-0134
Email: shelly.pearce@siemens.com

SUBMISSION DATE

November 18, 2016

TRADE NAME

ACUSON AcuNav Volume Intracardiac Echocardiography Catheter

COMMON NAME

Ultrasound Catheter

CLASSIFICATION NAME/PRODUCT CODE

Intravascular Ultrasound Catheter/OBJ

CLASSIFICATION

Class II, 21 CFR 870.1200

PREDICATE DEVICE

The AcuNav Volume is substantially equivalent to the AcuNav V diagnostic ultrasound 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.

INDICATIONS FOR USE

The AcuNav Volume is intended for imaging guidance, not treatment delivery, of cardiac interventional percutaneous procedures; intraluminal visualization of great vessel anatomy and physiology; intracardiac visualization of cardiac anatomy, physiology, and devices within the heart of an adult or a pediatric patient.

DESCRIPTION OF MODIFICATION

This is the initial release of the ACUSON AcuNav Volume Intracardiac Echocardiography Catheter

SUMMARY OF NONCLINICAL TESTS

To support the design change of the catheter, Design Verification Testing was performed on the modified ACUNAV VOLUME CATHETER.

Safety and Electromagnetic Compliance testing was also performed to support the design changes on the predicate device. The Safety and Electromagnetic compliance testing validates the use of the modified device.

SUBSTANTIAL EQUIVALENCE CONCLUSION

The AcuNav Volume diagnostic ultrasound catheter is substantially equivalent to the company's own previously cleared Acuson AcuNav V diagnostic ultrasound catheter (K081808) with regard to both intended use and technological characteristics. Both the subject catheter and the predicate catheter functions in the same manner as all diagnostic ultrasound catheters.

Feature / Characteristic	**AcuNav Volume** *This Submission*	**AcuNav V** *K081808*
Indications for Use:		
▪ Cardiac	√	√
▪ Pediatric	√	√
▪ Intraluminal	√	√
▪ Intraoperative	√	√
▪ 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 device 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 60601-1-1
  - EN/IEC 60601-1-2
- ISO 10993-1 Biocompatibility

Cleared patient contact materials and mechanical safety are unchanged.

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

Because the AcuNav Volume 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.

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 13485:2003 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. Therefore it is the opinion of Siemens Medical that the ACUSON AcuNav Volume ICE Catheter is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

SIMILARITIES TO THE PREDICATE DEVICES

a) The modified ACUNAV VOLUME is ***identical*** to the currently cleared ACUNAV V in the following aspects:

- Have the same intended use
- Use the same operating principle
- Are manufactured in the same manufacturing facility
- Use the same fundamental scientific technology
- Incorporate the same materials and construction
- Have the same deflection mechanism
- Catheter body & strain relief have identical assembly process

- Have the same acoustic array location and connection
- Are packaged using the same materials and processes
- Have the same Electronics; the PCB is inside the Hypertronic connector and Extension Cable
- Identical magnetic sensor location (not connected to the Printed Circuit Board (PCB))
- Have the same handle material
- Have the same Steering mechanism
- Have identical Hypertronic connector
- Most of the manufacturing processes are identical
- Have the same shelf life
- Use the same sterilization method (EtO sterilization)
- Are single use devices

DIFFERENCES FROM THE PREDICATE DEVICES

Some of the differences between the modified ACUNAV VOLUME CATHETER and the currently cleared ACUNAV V CATHETER are:

a) Tip dimensions
b) Distal shaft dimension
c) Electrical connector
d) Packaging

	AcuNav V	AcuNav Volume
Tip Dimensions	10F	12.5F
Distal Shaft Dimensions	10F	12.5F
Electrical Connector	Twist and lock mechanism	Push and lock mechanism
Packaging	Paper board tray	Paper board tray
	Double Pouch	Single Pouch
	Telescoping two-piece CCSBS unit carton	Non-telescoping one-piece CCSBS unit carton