



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 15, 2017

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

Re: K170992

Trade/Device Name: AcuNav V 10F Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: March 10, 2017
Received: April 3, 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light blue, semi-transparent "FDA" watermark.

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170992

Device Name

AcuNav V 10F Diagnostic Ultrasound Catheter

Indications for Use (Describe)

The catheter is intended for intra-cardiac 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.

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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

March 10, 2017

TRADE NAME

AcuNav V 10F Diagnostic Ultrasound Catheter

COMMON NAME

Diagnostic Ultrasound Catheter

CLASSIFICATION NAME/PRODUCT CODE

Intravascular Ultrasound Catheter/OBJ

CLASSIFICATION

Class II, 21 CFR 870.1200

PREDICATE DEVICE

#K081808, ACUSON AcuNav V 10F Ultrasound Catheter

DESCRIPTION OF MODIFIED DEVICE

The AcuNav V ultrasound catheter is sterile, disposable, and licensed for single use only. The catheter is optimized for intracardiac scanning. With the catheter, the physician can maneuver the imaging plane located inside the catheter tip to see the region of interest. The physician can steer the catheter to optimize tissue visualization.

The catheters are to be used only on systems with which they have been tested and found compatible. Each of these system/transducer combinations shall be cleared through the 510(k) process and have a subsequent special report submitted.

INDICATIONS FOR USE

The catheter is intended for intra-cardiac 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 V ultrasound catheter is substantially equivalent to the company's own previously cleared AcuNav V 10F Ultrasound Catheter (K081808) with regard to both intended use and technological characteristics. Both the subject catheters and the predicate catheters function in the same manner as all diagnostic ultrasound catheters.

Feature/Characteristic	AcuNav V <i>This Submission</i>	AcuNav V <i>K081808</i>
Indications for use:		
- Cardiac	√	√
- Pediatric	√	√
- Intra-luminal	√	√
- Intra-cardiac	√	√
Mode of operation:		
- 2D	√	√
- C	√	√
- D	√	√
- Volume	√	√
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 V 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 13485:2003 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 AcuNav V Ultrasound Catheters are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.