October 28, 2023

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

Re: K233270
Trade/Device Name: AcuNav Crystal Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: September 28, 2023
Received: September 29, 2023

Dear Bongsoo Cho:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Aneesh S. Deoras -S

Aneesh Deoras
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233270

Device Name
AcuNav Crystal Ultrasound 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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510k 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

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

OFFICIAL CORRESPONDENT

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SUBMISSION DATE

September 28, 2023

TRADE NAME

AcuNav Crystal Ultrasound Catheter

COMMON NAME

Ultrasound Catheter

CLASSIFICATION NAME/PRODUCT CODE

Diagnostic Intravascular Catheter/ OBJ

CLASSIFICATION

Class II, 21 CFR 870.1200

PREDICATE DEVICE

#K170263, AcuNav Diagnostic Ultrasound Catheter 8F, 10F

DESCRIPTION OF MODIFIED DEVICE

The AcuNav Crystal Ultrasound catheter is 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 catheter is to be used only on systems with which they have been tested and found compatible.

INDICATIONS FOR USE

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.

SUBSTANTIAL EQUIVALENCE CONCLUSION

The AcuNav Crystal Ultrasound catheter is substantially equivalent to the company's own previously cleared AcuNav Diagnostic Ultrasound Catheter 8F, 10F (K170263) with regard to both intended use and technological characteristics. The Indications for Use and Intended Uses of the submission device remain unchanged from the predicate catheter device as cleared under K170263. Both the subject catheter and the predicate catheter function in the same manner as all diagnostic ultrasound catheters.

ATTRIBUTES	**AcuNav Crystal Ultrasound Catheter** *This Submission*	**AcuNav Diagnostic Ultrasound Catheter** *Predicate (K170263)*
BACKGROUND		
Device name	AcuNav Crystal Ultrasound Catheter	AcuNav Diagnostic Ultrasound Catheter 8F/10F
510(k)	Subject of this 510(k) submission	K170263
Manufacturer	Siemens Medical Solutions USA, Inc. 22010 S.E. 51st Street Issaquah, WA 98029, USA	Siemens Medical Solutions USA, Inc. 22010 S.E. 51st Street Issaquah, WA 98029, USA
Manufacturing Facility	Siemens Healthineers Ltd. 2nd & 3rd Venture Bld., Pohang Technopark, 394, Jigok-ro, Nam-gu, Pohang-si, Gyeongsangbuk-Do, Republic of Korea	Siemens Healthineers Ltd. 2nd & 3rd Venture Bld., Pohang Technopark, 394, Jigok-ro, Nam-gu, Pohang-si, Gyeongsangbuk-Do, Republic of Korea
Indications for Use	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.	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.
INDICATIONS FOR USE		
Cardiac	X	X
Pediatric	X	X
Intra-luminal	X	X
Intra-Cardiac	X	X
MODE OF OPERATION		
2D	X	X
M	X	X
C	X	X
D	X	X
CW	X	X
PRINCIPLE OF OPERATION		
Mechanism of Distal tip Orientation	Manual Control knobs on the handle provide bidirectional steering capabilities in 2 planes, left/right and posterior	Manual Control knobs on the handle provide bidirectional steering capabilities in 2 planes, left/right and posterior

ATTRIBUTES	AcuNav Crystal Ultrasound Catheter *This Submission*	AcuNav Diagnostic Ultrasound Catheter *Predicate (K170263)*
(steering control)	/anterior.	/anterior.
MECHANICAL DESIGN CHARACTERISTICS		
Tip Dimensions	9F	8F, 10F
Insertable Length	90 cm	90 cm
Function of handle	The handle houses the steering mechanism that enables deflection of the distal tip	The handle houses the steering mechanism that enables deflection of the distal tip
OTHER DESIGN CHARACTERISTICS		
Radiopacity	Yes	Yes
Biocompatibility	Compliant to ISO 10993-1	Compliant to ISO 10993-1
Adhesives	N/A - no patient contacting materials have adhesives associated. Internal sub-assemblies inside the handle are bonded using adhesives	N/A - no patient contacting materials have adhesives associated. Internal sub-assemblies inside the handle are bonded using adhesives
Sterilization Method	EtO	EtO
Single Use	Yes	Yes

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, sterilization, packaging, shelf life 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:

- ISO 14971 risk management to medical devices
- ANSI/AAMI ES 60601-1 Safety Requirements for Medical Equipment
- IEC 60601-1-2 EMC requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- 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

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

Because the AcuNav Crystal Ultrasound catheter in this submission uses the same intended use, technology 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.

Therefore, it is opinion of Siemens Medical Solutions USA, Inc. that AcuNav Crystal Ultrasound catheter is substantially equivalent with the respect to safety and effectiveness to the device currently cleared for market.