October 17, 2025

SureAx Medical, LLC
Natalie Eagleburger
SureAx Regulatory Consultant
Starlight Medical Consulting
203 Providence Falls Trl
Hurdle Mills, North Carolina 27541

Re: K250203
Trade/Device Name: SureAx-Guide™ Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 19, 2025
Received: September 19, 2025

Dear Natalie Eagleburger:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2025.10.17 16:14:41 -04'00'

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250203

Device Name
SureAx-Guide Guidewire

Indications for Use *(Describe)*
The SureAx-Guide guidewire is indicated for use in facilitating delivery of percutaneous catheters into the peripheral vasculature. The SureAx-Guide guidewire is not intended for use in the coronary or neuro vasculature.

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
K250203

SureAx-GUIDE™ Guidewire
Traditional 510(k)

I. SUBMITTER

SureAx Medical™ LLC
11107 Roselle St.,
San Diego, CA 92121 USA

Phone: 858-249-7402
Contact Person: Ricardo Villanueva
Date Prepared: September 19, 2025

II. DEVICE

Trade Name:	SureAx-Guide™ Guidewire
Common or Usual Name:	Wire, Guide, Catheter
Classification Name:	Catheter guide wire
Regulatory Class:	Class II
Product Code and Regulation:	DQX, 21 CFR 870.1330

III. PREDICATE DEVICE

Primary Predicate

COOK Inc- Approach Hydro ST Guidewire (K091385)

IV. DEVICE DESCRIPTION

The SureAx-Guide™ guidewire is comprised of a stainless-steel wire with a PTFE coating and distal coils and soldered tip. The distal end has a urethane sheath and PVP-based hydrophilic coating. The maximum outside diameter is 0.0142 inches and it will be available in 135cm and 190cm lengths. It will be supplied sterile and intended for single use.

V. INDICATIONS FOR USE

The SureAx-Guide™ guidewire is indicated for use in facilitating delivery of percutaneous catheters into the peripheral vasculature. The SureAx-Guide™ guidewire is not intended for use in the coronary or neuro vasculature.

A comparison of the indications for use of the proposed device and the predicate device is provided in the table below:

Characteristic	Subject Device SureAx-Guide™ Guidewire	Predicate Device Approach Hydro ST Guidewire (K091385)	Equivalence Comparison
Indications for Use	The SureAx-Guide™ guidewire is indicated for use in facilitating delivery of percutaneous catheters into the peripheral vasculature. *The SureAx-Guide™ guidewire is not intended for use in the coronary or neuro vasculature.*	The Approach Hydro ST Guidewire is indicated for use in facilitating delivery of percutaneous catheters into the peripheral vasculature.	Equivalent

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The design of the SureAx-Guide Guidewire and the predicate Approach Hydro ST Guidewire are the same in materials, coatings, critical dimensions, and sterility assurance level. The key technological difference is that the SureAx Guide Guidewire is sterilized via radiation (gamma) while the predicate is sterilized via Ethylene Oxide. The results from preclinical evaluations and performance bench testing demonstrate that the SureAx-Guide's technological and performance characteristics meet defined design requirements and can perform in a manner equivalent to the predicate for its intended use. Performance data demonstrates the SureAx-Guide performs as intended and is substantially equivalent to its predicate.

A comparison of the technological characteristics of the subject device and the predicate device is provided in the table below:

Characteristic	Subject Device SureAx-Guide™ Guidewire	Predicate Device Approach Hydro ST Guidewire (K091385)	Equivalence Comparison
Trade Name	SureAx-Guide	Approach Hydro ST Guidewire	N/A
Product Code	DQX	DQX	Same
Regulation Number	21 CFR 870.1330	21 CFR 870.1330	Same
Regulatory Class	II	II	Same
Nominal Wire Outer Diameter	0.014"	0.014"	Same
Overall Length	135, 190cm	135, 190, 300cm	Same
Tip Length	13.5cm	13.5cm	Same
Tip Shape	Straight	Straight	Same
Wire material	Stainless steel	Stainless steel	Same
Coating(s)	• Proximal: PTFE hydrophobic • Distal: PVP-based hydrophilic	• Proximal: PTFE hydrophobic • Distal: PVP-based hydrophilic	Same
Tip Material	Stainless steel and platinum/nitinol	Stainless steel and platinum/nitinol	Same
Accessories	None	None	Same
Packaging Configuration	• Hooped guidewire within sterile barrier pouch • Unit box	• Hooped guidewire within sterile barrier pouch • Unit box	Same
Sterilization	Single use Provided sterile via radiation (gamma) to SAL 10^{-6}	Single Use Provided sterile via Ethylene Oxide to SAL 10^{-6}	Equivalent
Shelf Life	2 years	2 years	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Preclinical tests were conducted on the SureAx-Guide Guidewire to demonstrate that it meets defined

design requirements and can perform in a manner equivalent to its predicate. Testing included comparative bench and preclinical testing per relevant recognized consensus standards where applicable and as defined in the table below. The design, testing, and technical information provided for the SureAx-Guide Guidewire also comply with applicable standards and recommendations for its product code as defined in:

- Recognized Consensus Standard: 3-172 AAMI TIR42:2021 Evaluation of Particulates Associated with Vascular Medical Devices.
- FDA Guidance Document: Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings – Labeling Considerations (issued 10 October 2019).
- FDA Guidance Document: Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling (issued October 10, 2019).

The table below summarizes the performance testing conducted.

Test	Reference Standards OR Test Method Summary	Results and Conclusions
Biocompatibility per ISO 10993-1 for an external communicating device, limited (<24 hour) direct blood contacting device.	Cytotoxicity per ISO 10993-5	All results met acceptance criteria and demonstrate the SureAx-Guide is non-cytotoxic.
	Sensitization per ISO 10993-10	All results met acceptance criteria and demonstrate the SureAx-Guide is a non-sensitizer.
	Intracutaneous reactivity per ISO 10993-23	All results met acceptance criteria and demonstrate the SureAx-Guide is a non-irritant.
	Systemic toxicity per ISO 10993-11	All results met acceptance criteria and demonstrate the SureAx-Guide is non-toxic.
	Sc5b-9 complement activation per ISO 10993-4	All results met acceptance criteria and demonstrate the SureAx-Guide is not an activator.
	Direct and indirect hemolysis per ISO 10993-4	All results met acceptance criteria and demonstrate the SureAx-Guide is non-hemolytic.
	Thrombogenicity studies, including Phospholipid Platelet Test (PTT) and Platelet Leukocyte Test (PLC), per ISO 10993-4	All results met acceptance criteria and demonstrate the SureAx-Guide is thromboresistant.
Sterilization	Evaluated per ANSI/AAMI/ISO 11137-1 including establishing the sterility assurance level (SAL) and evaluating bioburden	Terminal sterilization validation testing supports a 10^{-6} SAL, equivalent to that of the predicate device.
Pyrogenicity / Endotoxin	Material-mediated pyrogenicity (USP rabbit pyrogen test) per ISO 10993-11 and limulus amebocyte lysate (LAL) evaluation	All results met acceptance criteria and demonstrate the SureAx-Guide is non-pyrogenic.
Packaging	Sterile barrier and labeling performance evaluation following simulated environmental conditioning per ASTM D4332 and distribution conditioning per ASTM D4169 DC 13 Lvl 1.	All testing passed
Shelf Life	Performance evaluation conducted on aged devices and packaging. Aging conducted per ASTM F1980 and applicable standards with real time confirmatory studies completed in parallel or via real time studies alone.	Results support expiration dating on the labeling.
Radiopacity	Evaluated *in vivo* per ASTM F640	All results met acceptance criteria and demonstrate the SureAx-Guide is radiopaque, is suitable for its intended use, and is substantially equivalent to the predicate device

Test	Reference Standards OR Test Method Summary	Results and Conclusions
Non-clinical bench testing	• Visual inspection • Pouch peel strength • Dimensional verification • Coating lubricity • Simulated use conditioning • Trackability • Particulate evaluation • Coating integrity • Coating durability • Tip flexibility • Torqueability • Torque strength • Kink resistance • Tip pull • Tensile strength • Corrosion resistance	All results met acceptance criteria and demonstrate the SureAx-Guide is suitable for its intended use and is substantially equivalent to the predicate device.

Manufacturing and traceability of devices tested were conducted in accordance with 21 CFR Part 820 Good Manufacturing Practices. In all instances, the SureAx-Guide Guidewire functioned as intended and the results observed were as expected. These test results confirm that SureAx-Guide Guidewire complies with the recognized standards, meets the design specifications and performance requirements for the intended use, and is substantially equivalent to the predicate.

VIII. CONCLUSIONS

The SureAx-Guide Guidewire is substantially equivalent to the Approach Hydro ST Guidewire predicate device (K091385). The SureAx-Guide Guidewire and its predicate share the same Product Code and classification as a Catheter guide wire. The SureAx-Guide Guidewire has the same intended use and indications for use as the predicate device. The SureAx-Guide Guidewire also has the same design and similar technological characteristics as the predicate device. Minor differences in technological characteristics do not raise different questions of safety and efficacy compared to the predicate.

The results from preclinical evaluations demonstrate that the technological and performance characteristics of the SureAx-Guide Guidewire meet defined design requirements. Performance and preclinical data demonstrate that the SureAx-Guide Guidewire performs as intended and is substantially equivalent to its predicate. This conclusion is based upon equivalence in the device's (1) design, (2) material technological characteristics, (3) technological characteristics, (4) principles of operation, (5) and intended use.