July 14, 2026

SP Medical A/S
Philip Davenport
Regulatory Specialist
Møllevej 1
Karise, DK-4653
Denmark

Re: K253667/S001
Trade/Device Name: Accoat Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 6, 2025
Received: June 12, 2026

Dear Philip Davenport:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

LYDIA S. GLAW -S
Digitally signed by LYDIA S. GLAW -S
Date: 2026.07.14 16:48:33 -04'00'

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)*
K253667

Device Name
Accoat Guide Wire

Indications for Use *(Describe)*
The Accoat Guide Wire is intended to facilitate placement of devices during diagnostic and interventional procedures. It is not intended for use in the coronary vasculature or neurovasculature.

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.

510(k) Summary for K253667
Date Prepared: June 10, 2026

Submitted by:
Philip Davenport
Regulatory Specialist

Manufacturer:
SP Medical A/S
Møllevej 1, Karise, DK-4653 Denmark
+45 56 76 60 00
info@sp-medical.dk

Device information:

Trade name:	Accoat Guide Wire
Common name:	Guide wire
Classification name:	Wire, Guide, Catheter
Regulatory Class:	Class II
Product code:	DQX
Regulation:	21 CFR 870.1330
Classification Panel:	Cardiovascular

Predicate device:
The Cook Fixed Core Wire Guide (K171764) is a fixed core guide wire intended to facilitate placement of devices during diagnostic and interventional procedures. It is cleared under regulation 21 CFR 870.1330.

Reference devices:
Reference devices are the Cook Double Flexible Tipped Wire Guides (K171912) and the Amplatz Moveable Core Guidewire (K864058). These are cleared under regulation 21 CFR 870.1330.

Device description:
The Accoat Guide Wire is a guide wire with a flexible stainless-steel coil and a stainless-steel core. It is optionally available with a hydrophobic PTFE coating. It is available in lengths from 20cm to 450cm. It is available in a range of diameters from 0.018” to 0.038”. Shaft stiffnesses may be standard, stiff, extra stiff or super stiff. Wire tips may be straight, or with a J-Tip with a radius of 1.5mm to 15mm.

A double-ended variant is available where either the distal and proximal end of the wire may be introduced into the patient. A moveable core variant is available where the stiffness at the distal end may be adjusted in the procedure by withdrawing or advancing a handle at the proximal end.

The guide wire is supplied in a dispenser with a luer lock and straightener, placed within a peel pouch. The product is supplied sterile, via ethylene oxide sterilization. The device is supplied in a product box containing 10 peel pouches and an IFU. The peel pouch and product box are labelled.

Intended use
The Accoat Guide Wire is intended to facilitate placement of devices during diagnostic and interventional procedures. It is not intended for use in the coronary vasculature or neurovasculature.

Indications for use:
The Accoat Guide Wire is intended to facilitate placement of devices during diagnostic and interventional procedures. It is not intended for use in the coronary vasculature or neurovasculature.

Technological comparison to predicate and reference devices:

Feature	Accoat Guide Wire	Cook Fixed Core Wire Guide	Cook Double Flexible Tipped Wire Guides	Amplatz Moveable Core Guidewire	Comment
Device	Subject device	Predicate device	Reference Device	Reference Device	N/A
Product code	DQX	DQX	DQX	DQX	No difference
Regulation	870.1330	870.1330	870.1330	870.1330	No difference
Class	2	2	2	2	No difference
510(k) reference	K253667	K171764	K171912	K864058	N/A
Intended use	Intended to facilitate placement of devices during diagnostic and interventional procedures.	Intended to facilitate placement of devices during diagnostic and interventional procedures.	Intended to facilitate placement of devices during diagnostic and interventional procedures.	intended for use in the percutaneous introduction of catheters.	Substantially equivalent. No difference to predicate device. All devices are intended to enable percutaneous introduction of vascular devices.
Area of use	Peripheral vasculature. Coronary and neurovascular use excluded.	Peripheral vasculature. Coronary and neurovascular use excluded.	Peripheral vasculature. Coronary and neurovascular use excluded.	Angiographic use.	Substantially equivalent. No difference to predicate device. Narrower definition than reference device.
Wire Length	20cm – 450cm	15cm – 480cm	30cm – 260cm	125cm - 150cm	Substantially equivalent. Within subset of predicate and reference devices.
Wire Diameter	0.018” – 0.038”	0.018” – 0.038”	0.015” – 0.038”	0.035” – 0.038”	Substantially equivalent. Within subset of predicate and reference devices.
Tip type	Straight 1.5mm – 15mm J Tip	Straight 3mm – 15mm	Straight 3mm J Tip	Straight 3mm – 15mm J Tip	Substantially equivalent. Similar in size and function to predicate and reference devices.
Wire material	Stainless steel	Stainless steel	Stainless steel	Stainless steel	No difference
Coating	Uncoated or PTFE	Uncoated or PTFE	Uncoated or PTFE	Uncoated or PTFE or Heparin	Substantially equivalent. No difference to predicate. Within range of reference device.
Packaging	Dispenser in a peel pouch.	Dispenser in a peel pouch.	Dispenser in a peel pouch.	Dispenser in a peel pouch.	No difference
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide	Ethylene oxide	No difference
Shelf life	5 years	5 years	5 years	5 years	No difference

The differences of the subject device in comparison to the predicate device are Accoat Guide Wire is available in a double ended tip configuration and a movable core configuration.

Performance testing:
The Accoat Guide Wire has been tested to demonstrate that the relevant design and performance requirements have been met, and the results support a determination of substantial equivalence to the predicate device. The following tests have been performed:

- Visual examination
- Dimensional verification
- Simulated use
- Tensile strength
- Tip pull
- Torque strength
- Torqueability
- Coating integrity
- Particulate evaluation
- Lubricity
- Corrosion resistance
- Kink resistance
- Tip flexibility
- Radiopacity

Additional testing:
Additional testing has also been carried out to demonstrate the effective use of the subject device. These include:

- Sterility testing
- Transportation testing
- Peel pouch seal strength and seal integrity testing

Biocompatibility testing:
The Accoat Guide Wire is considered an external-communicating device, in contact with circulating blood for a limited duration (<24 hours) according to ISO 10993-1. Accordingly, the following biocompatibility testing was performed:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Material-mediated pyrogenicity
- Acute systemic toxicity
- Partial thromboplastin time
- Complement activation
- Hemolysis
- Platelet and leukocyte count
- Comparative surface assessment

Conclusion:
The results of the tests performed support the conclusion that the Accoat Guide Wire met the design input requirements based on the stated intended use, and that these devices do not raise new issues of safety or effectiveness. They support determination that the subject device is substantially equivalent to the predicate device.