March 16, 2026

Shanghai Achieva Medical Suzhou Co., Ltd.
% Christine Zeng
Sr. RA Manager
SUZHOU MDCE Co., Ltd.
Room 03-1, Floor 20, Building 2, 10 Yueliangwan Road,
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China

Re: K252122
Trade/Device Name: DCwire Micro-guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: February 13, 2026
Received: February 13, 2026

Dear Christine Zeng:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

NAIRA MURADYAN -S

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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)*
K252122

Device Name
DCwire Micro-guidewire

Indications for Use *(Describe)*
The DCwire Micro-guidewire is intended for general intravascular use, including neuro and peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and 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.

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510(k) Summary K252122

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Date Prepared: Mar. 12, 2026

Device Name and Classification

Trade/Proprietary Name: DCwire™ Micro-guidewire

Common Name: Micro-guidewire

Classification Name: Wire, Guide, Catheter, 21 CFR 870.1330 – Class II

Product Code: MOF, DQX

Legally Marketed Predicate Devices

Primary Predicate Device	
K202522	*Synchro SELECT™ Guidewire*
Predicate Device	
K032146	*PVS 1300 Synchro® 0.014" & PVS 1600 Synchro® 0.010" Guidewires*

Device Description

The DCwire™ Micro-guidewire is a single-use device with a shapeable tip, used to gain intravascular access and facilitate the positioning and exchange of interventional devices in small diameter, tortuous vasculature for peripheral and neuro diagnostic and interventional procedures. The Micro-guidewire can be torqued to facilitate navigation through the vasculature.

DCwire™ Micro-guidewire comes in three stiffness profiles: Soft, Standard, and Support.

Accessories

The DCwire™ Micro-guidewire is provided with two (2) accessories, an Introducer and a Torque Device.

Indications for Use

The DCwire™ Micro-guidewire is intended for general intravascular use, including neuro and peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neuro vasculature.

Technological Characteristics and Product Feature Comparison

The DCwire™ Micro-guidewire is substantially equivalent to the Predicate devices, the Synchro SELECT™ Guidewire, cleared under **K202522**, and the PVS 1600 Synchro® 0.010" Guidewire, cleared under **K032146**, based on the following:

- Same intended use
- Same fundamental materials, design and technology
- Same operating principles
- Similar sterilization method and process for devices

A comparison of the Subject device with the Predicate devices is summarized in **Table 1** below.

Table 1. Comparison of Subject Device to Predicate Devices

Characteristic	Primary Predicate Device	Predicate Device	Subject Device
Device	Synchro SELECT™ Guidewire (K202522)	PVS 1300 Synchro 0.014" & PVS 1600 Synchro® 0.010" Guidewires (K032146)	DCwire™ Micro-guidewire (K252122)
Classification	Class II	Class II	Same
Product Code	MOF, DQX	DQX	MOF, DQX
Regulation Number	21 CFR 870.1330	21 CFR 870.1330	Same
Review Panel	Neurology, Cardiovascular	Cardiovascular	Neurology, Cardiovascular

Characteristic	Primary Predicate Device	Predicate Device	Subject Device
Indications for Use	The Synchro SELECT Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.	The PVS 1300 Synchro® 0.014" & PVS 1600 Synchro® 0.010" Guidewire series of products are intended for general intravascular use, including the neuro and peripheral vasculature. The device can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.	DCwire™ Micro-guidewire is intended for general intravascular use, including neuro and peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neuro vasculature.
Device Description/ Principle of Operation	The Synchro SELECT Guidewire is a single-use device with a shapeable tip, used to gain intravascular access to facilitate the positioning and exchange of interventional devices in small diameter, tortuous vasculature for neuro and peripheral diagnostic and interventional procedures. The wire can be torqued to facilitate navigation through the vasculature.	Same	Same
Patient Population	Patients undergoing endovascular treatment in neuro and peripheral vasculature.	Same	Same
Accessories	Guidewire Introducer, Torque Device	Guidewire Introducer, Torque Device	Same
Diameter	Distal: 0.014 inch Proximal: 0.014 inch	PVS 1300 Synchro® 0.014" Guidewire: Distal: 0.014 inch Proximal: 0.014 inch PVS 1600 Synchro® 0.010" Guidewire: Distal: 0.010 inch Proximal: 0.012 inch	10 Series: Distal: 0.010 inch Proximal: 0.012 inch 14 Series: Distal: 0.014 inch Proximal: 0.014 inch

Characteristic	Primary Predicate Device	Predicate Device	Subject Device
Core Wire	304 Stainless Steel, PTFE Coated on the proximal section	304 Stainless Steel, PTFE Coated on the proximal section	Same
Core Wire Length	215cm Access Length 300cm Exchange Length	180 – 300cm	215cm and 300cm Effective Lengths
Guidewire Tip	Nickel-Titanium, Micro-Machined Nitinol	Nickel-Titanium, Micro-Machined Nitinol	Same
Radiopaque Coil	Platinum	Platinum	Platinum-Tungsten Alloy
Adhesive	UV Curable Adhesive	Limited information	Epoxy Glue UV Curable Glue
Primer	Parylene Dimer	Limited information	None
Hydrophilic Top Coating	Proprietary Hydrophilic Top Coating	Hydrophilic Polymer	Polyvinylpyrrolidone
Hydrophilic Base Coating	Proprietary Hydrophilic Base Coating	Hydrophilic Polymer	Polyurethane
Dispenser Hoop	High Density Polyethylene	Limited information	High Density Polyethylene
Accessory Card	Clay Coated Solid Bleached Sulfate (CCSBS)	Limited information	PVC
Sterile Pouch	Tyvek-Polyethylene	Limited information	Tyvek-Polyethylene/ Polyethylene terephthalate
Shipping Carton	Solid Bleached Sulphate (SBS)	Limited information	5-ply AB flute corrugated cardboard
Sterilization Method	Ethylene Oxide (EO) gas	Irradiation	EO gas
How Supplied	Single Use/Sterile	Single Use/Sterile	Same

The differences between the devices do not raise new questions of safety and effectiveness.

Bench Performance Testing

The results of the bench testing conducted on the subject device demonstrate that it performs as intended and meets design specifications. Bench performance testing included the following:

Table 2. Bench Testing Summary

Test name	Test Method Summary	Conclusions
Dimensional Verification	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Verified key dimensions of the guidewire.	Acceptance criteria were met.
Visual Inspection	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Ensure devices are free of defects that could cause trauma to vessels during use.	Acceptance criteria were met.
Simulated Use	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Guidewires were tested for use with a microcatheter, the guidewire introducer, and torque device while navigating to target locations in a tortuous simulated use model.	Acceptance criteria were met.
Tensile Strength	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Measured the force required to break at bond.	Acceptance criteria were met.
Tip Pull	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Evaluated the tensile force required to separate the distal tip from the guidewire for guidewires with joints at the tip.	Acceptance criteria were met.
Torque Strength	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019).	Acceptance criteria were met.

	Record the angle the proximal end of the wire can be rotated until it exceeds its maximum rotations and fails.	
Torqueability	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling" (2019). Measured starting angle and rotation efficiency when proximal end is rotated.	Acceptance criteria were met.
Coating Integrity	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires –Performance Tests and Recommended Labeling" (2019).Visually inspect and compare hydrophilic coating before and after tracking through a tortuous simulated use model. Additionally, visually inspect device coating after staining the devices.	Acceptance criteria were met.
Particulate Evaluation	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Counted particulates of various size ranges after tracking through a tortuous simulated use model.	Acceptance criteria were met. Comparable to the predicate.
Coating Lubricity	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Hydrophilic coating lubricity was assessed after multiple pull cycles through silicone pads.	Acceptance criteria were met.
Corrosion Resistance	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). The metal part of the Micro-guidewire should show no signs of corrosion on its surface after the corrosion resistance test	Acceptance criteria were met.
Kink Resistance	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019).	Acceptance criteria were met.

	Demonstrate the device's resistance to kinking when bent around anatomically relevant radii.	
Tip Flexibility	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Measured the force required to deflect the guidewire tip when held at specific gauge lengths.	Acceptance criteria were met.
Radiopacity	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Ensure radiopaque markers or portions are visible using clinical imaging techniques.	Acceptance criteria were met.
Coating Durability	Coating durability was assessed after repeated pull cycles through silicone pads.	Acceptance criteria were met.
Tip Shapeability, Tip Shape Retention	Shaped the guide wire to a specific angle and unshaped for a total of 5 times, check under 40x magnification to ensure there is no rupture or damage of any kind. Measure the immediate angle after shaping, and the tip shape retention after tracking the guidewire through a tortuous simulated use model.	Acceptance criteria were met.
Tip Integrity	Shape, straighten and reverse reshape the guide wire for a total of 5 times, then perform simulated use, check under 40x magnification to ensure there is no rupture or damage of any kind.	Acceptance criteria were met.
Flexure	Subjected the guidewire to multiple flexure cycles around cylindrical pins.	Acceptance criteria were met.
Fracture	Subjected the guidewire to multiple wrappings around cylinder and visually inspected for signs of fracture.	Acceptance criteria were met.
Torque Device - Appearance	Ensure appearance of the Torque Device is clean and free of impurities.	Acceptance criteria were met.
Torque Device -Fixed Strength of Micro-guidewire	Ensure that the torsion has no axial slippage.	Acceptance criteria were met.

Torque Device - Fixable Dimension	Ensure the Torque Device can lock the proximal end of the micro-guidewire and drive the micro-guidewire to rotate.	Acceptance criteria were met.
Torque Device - Micro-guidewire Damage	Ensure the Torque Device does not cause visually observable damage to the micro-guidewire.	Acceptance criteria were met.
Torque Device - Torque Slip Force	Ensure that the torsion has no circular slippage.	Acceptance criteria were met.
Introducer - Visual Inspection	Ensure the appearance of the Introducer is clean and free of impurities.	Acceptance criteria were met.
Introducer - Dimensional Verification	Ensure the dimensions of the Introducer comply with specifications.	Acceptance criteria were met.
Introducer - Functionality	Ensure the Introducer can assist in guiding the micro-guidewire into the microcatheter.	Acceptance criteria were met.

Sterilization and Shelf-Life Testing

The device is provided sterile and it is sterilized by Ethylene Oxide. The sterilization process of Ethylene Oxide consists of four stages. The sterilization cycle was validated to achieve a sterility assurance level (SAL) of 10^{-6} according to ISO 11135:2014.

Accelerated aging was used to simulate the storage of 3 years for the DCwire™ Micro-guidewire, then the bench performance tests as well as the package integrity tests were performed on the accelerated aged samples and met the pre-determined acceptance criteria.

Performance Data - Animal, Clinical

No animal or clinical studies were conducted as the intended use and the fundamental scientific technology are the same as that of the predicate. Substantial equivalence of the subject device has been established to the predicate devices through the results of non-clinical performance testing.

Biocompatibility Testing

The DCwire™ Micro-guidewire is an externally communicating medical device directly contacting circulating blood for a limited (≤24 hours) duration. Therefore, as per "Table A.1: Biocompatibility Evaluation Endpoints" of FDA biocompatibility guidance, the following assessments were conducted.

Table 3. Biocompatibility Testing Summary

Test Item	Standard	Conclusion
MEM Elution Cytotoxicity Assay (ISO)	ISO 10993-5	Pass: Non-cytotoxic

Test Item	Standard	Conclusion
Sensitization-Guinea Pig Maximization Test (ISO)	ISO 10993-10	Pass: Non-sensitizing
Intracutaneous Reactivity Test (ISO)	ISO 10993-23	Pass: Non-reactive
Acute Systemic Toxicity Test (ISO)	ISO 10993-11	Pass: No evidence of acute systemic toxicity
Material Mediated Pyrogenicity Test (ISO/USP)	ISO 10993-11/ USP General Chapter <151>	Pass: Non-pyrogenic
Hemolysis Assay – Direct and Indirect (ISO)	ISO 10993-4/ ASTM F756	Pass: Non-hemolytic
Complement Activation Assay (ISO)	ISO 10993-4	Pass: No significant complement activation observed
Partial Thromboplastin Time (PTT) Assay (ISO)	ASTM F 2382	Pass: No significant effect on coagulation time
Heparinized Blood Platelet and Leukocyte Count Assay (ISO)	ASTM F2888	Pass: No significant impact on platelet and leukocyte counts
Thrombogenicity – Non-Anticoagulated Venous Implant Study in a Canine Model	ISO 10993-4	Pass: No evidence of thrombogenicity in canine model

Conclusion

The subject device is substantially equivalent to the predicate devices with regards to device design, materials, intended use, and patient population. The conclusions drawn from the non-clinical testing conducted demonstrate that the subject device performs as intended and is substantially equivalent to the predicate devices.