November 26, 2025

Arbor Endovascular, LLC
Kathy Tansey
Vice President of Regulatory, Clinical, and Quality
2345 Bering Drive
San Jose, California 95131

Re: K253168
Trade/Device Name: 0.014" Willow Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: October 29, 2025
Received: October 30, 2025

Dear Kathy Tansey:

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,

NAIRA MURADYAN -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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)*
K253168

Device Name
0.014" Willow Guidewire

Indications for Use *(Describe)*
The 0.014” Willow Guidewire 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 neuro vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and 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.

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510(k) Summary K253168

Submitter Name, Address and Contact:

Submitter: Arbor Endovascular, LLC
2345 Bering Drive
San Jose, CA 95131

Sponsor Contact: Kim Otto
Vice President, Operations
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Correspondent: Kathy Tansey
Vice President of Regulatory, Clinical, and Quality
Email: ktansey@arborendo.com
Phone: +1 (408) 391-6536

Date Prepared: November 24, 2025

Device Name and Classification:

Trade/Proprietary Name:	0.014" Willow™ Guidewire
Common Name:	Wire, Guide, Catheter
Classification Name:	Wire, Guide, Catheter, 21 CFR 870.1330 – Class II
Product Code:	MOF, DQX
Legally Marketed Predicate Device:	0.014" Willow™ Guidewire (K243756)

Device Description:

Like the predicate device, the 0.014" Willow Guidewire is a single-use product with a shapeable tip available in straight and pre-shaped configurations, 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. The 0.014" Willow Guidewire comes in three stiffness profiles: Soft, Standard and Support.

Accessories:

The 0.014" Willow Guidewire is provided with three (3) accessories, an Introducer, a Torque Device and a Shaping Mandrel.

Indications for Use:

The Indications for Use for the 0.014" Willow Guidewire are the same as for the predicate device and are as follows:

The 0.014" Willow Guidewire 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 neuro vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

Technological Characteristics and Product Feature Comparison:

The 0.014" Willow Guidewire is substantially equivalent to the predicate device based on the following:

- Same indications for use
- Same fundamental materials and similar manufacturing process
- Same fundamental design and technology
- Same operating principles
- Same materials and processes for packaging
- Same sterilization method and process for devices

A comparison of the subject device with the predicate device is summarized in **Table 1** below.

Table 1. Substantial Equivalence Comparison

Characteristic	Predicate Device 0.014" Willow Guidewire (K243756)	Subject Device 0.014" Willow Guidewire (K253168)
Classification Name	Wire, Guide, Catheter, 21 CFR 870.1330, Class II	Same
Product Code	MOF, DQX	Same
Review Panel	Neurology	Same
510(k) Submitter	Arbor Endovascular, LLC 2345 Bering Drive San Jose, CA 95131	Same

Characteristic	Predicate Device 0.014" Willow Guidewire (K243756)	Subject Device 0.014" Willow Guidewire (K253168)
Indications for Use	The 0.014" Willow Guidewire 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 neuro vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.	Same
Device Description/ Principle of Operation	The 0.014" Willow Guidewire is a single-use product with a shapeable tip available in straight and pre-shaped configurations, 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
Target Population	Patients undergoing endovascular treatment, including in the neuro and peripheral vasculatures.	Same
Accessories	Guidewire Introducer, Torque Device, and Shaping Mandrel	Same
Core Wire	Cobalt chromium alloy with PTFE coating on the proximal section	Same
Core Wire Length	215 cm Access Length 315 cm Exchange Length	Same
Guidewire Tip (slotted tube)	Nitinol-Titanium Laser Cut Nitinol	Same
Radiopaque Coil	Platinum-Tungsten Alloy	Same
Radiopaque Coil Shapes and Lengths	Standard and Soft Straight and Pre-Shaped: Platinum/ Tungsten, 10 cm Support Straight and Pre-shaped: Platinum/ Tungsten, 3 cm	Same
Adhesive	UV Curable Adhesive	Same
Primer	Parylene Dimer	Same
Hydrophilic Coating	Proprietary Hydrophilic Coating	Same
Guidewire Introducer	Included	Same
Shaping Mandrel	Included	Same
Torque Device	Included	Same
Dispenser Hoop	High Density Polyethylene (HDPE)	Same
Accessory Card	HDPE	Same

Characteristic	Predicate Device 0.014" Willow Guidewire (K243756)	Subject Device 0.014" Willow Guidewire (K253168)
Sterile Pouch	Tyvek®/Nylon- Polyethylene	Same
Shipping Carton	Folding Box Board (FBB)	Same
Sterilization Method	100% Ethylene Oxide	Same
How Supplied	Single Use/Sterile	Same

The differences between the devices, including changes to the hypotube cutting pattern and distal tip of the core wire, and addition of a radiopaque marker, do not raise new questions of safety and effectiveness.

Risk Assessment:

Risk assessment of the 0.014" Willow Guidewire has been conducted in accordance with ISO 14971:2019 to show that no new risks were identified compared to the commercially available predicate device. Results of non-clinical testing have demonstrated the subject device is substantially equivalent to the predicate device.

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	Test Method Summary	Conclusions
Coating Lubricity	Hydrophilic coating lubricity was assessed after multiple pull cycles through silicone pads.	Acceptance criteria were met.
Coating Durability	Coating durability was assessed after repeating multiple pull cycles through silicone pads.	Acceptance criteria were met.
Coating Integrity	Testing completed per FDA guidance document "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" (2019). Coating integrity inspected pre- and post-simulated use tracking with comparison to predicate.	Coating integrity was reported and considered acceptable.
Corrosion Resistance	Testing completed per FDA guidance document "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" (2019).	Acceptance criteria were met.

Test	Test Method Summary	Conclusions
Dimensional and Visual Inspection	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.
Flex Fatigue	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.
Kink Resistance	Testing completed per FDA guidance document "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" (2019). Wrapped the guidewire around test fixture with clinically relevant radii.	Acceptance criteria were met.
Particulate Characterization	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, with comparison to the predicate device.	Particulate counts were reported and considered acceptable.
Radiopacity	Testing completed per FDA guidance document "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" (2019). Subject and predicate guidewires were evaluated under fluoroscopy.	All Willow Guidewires demonstrated acceptable radiopacity. The radiopacity of the subject device was comparable to that of the predicate device.
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 each bond, including distal tip.	Acceptance criteria were met.

Test	Test Method Summary	Conclusions
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 5 mm, 10 mm and 20 mm gauge lengths.	Acceptance criteria were met.
Tip Shapeability	Shaped the guidewire tip for a total of three (3) times per labeling.	Acceptance criteria were met.
Tip Shape Retention	Measured the tip shape retention after tracking the guidewire through a tortuous simulated use model.	Acceptance criteria were met.
Torqueability	Testing completed per FDA guidance document "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" (2019). Tracked the guidewire through a tortuous simulated use model and evaluated the torque response.	Acceptance criteria were met.
Torque Strength	Testing completed per FDA guidance document "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" (2019). Recorded the number of times the proximal end of the wire can be rotated until it exceeds its maximum rotations and fails.	Acceptance criteria were met.

Sterilization and Shelf-Life Testing:

The device and its accessories are sterilized by 100% Ethylene Oxide and have been adopted into the existing validated sterilization process in accordance with the principles of ISO 11135:2014 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices". A sterility assurance level (SAL) of 10^{-6} has been demonstrated. The performance testing completed supports a 1-year shelf-life.

Performance Data – Animal, Clinical:

No animal or clinical studies were conducted as the indications for 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 device through the results of non-clinical performance testing.

Biocompatibility Testing:

Biocompatibility testing was conducted on the 0.014" Willow Guidewire in accordance with FDA guidance document, "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process","* and

demonstrates that the guidewire and accessories meet biological safety requirements for externally communicating medical devices with direct circulating blood contact for ≤ 24 hours. This statement is supported by the standards assessment and the testing conducted by Arbor Endovascular.

Table 3: Summary of Biocompatibility Testing

Test	Test Method Summary	Conclusion
Acute Systemic Toxicity*	Per ISO 10993-11	Pass: No evidence of acute systemic toxicity
Complement Activation*	Per ISO 10993-4	Pass: Non-activator
Cytotoxicity – MEM Elution^	Per ISO 10993-5	Pass: Non-cytotoxic
Hemolysis - Direct and Indirect*	Per ISO 10993-4	Pass: Non-hemolytic
Intracutaneous Reactivity*	Per ISO 10993-10	Pass: Non-reactive
In Vivo Thrombogenicity^	Per ISO 10993-4	Pass: Non-thrombogenic
Pyrogenicity*	Per ISO 10993-11	Pass: Non-pyrogenic
Sensitization*	Per ISO 10993-10	Pass: Non-sensitizing

*Supported by testing conducted on the predicate device
^ Additional testing conducted using the subject device per biological evaluation report and risk assessment

Conclusion:

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