August 26, 2025

Imperative Care, Inc.
Shivani Patel
Principal Regulatory Affairs Specialist
1359 Dell Avenue
Campbell, California 95008

Re: K244061
Trade/Device Name: X-Wire Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: July 23, 2025
Received: July 24, 2025

Dear Shivani Patel:

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,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
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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)*
K244061

Device Name
X-Wire Guidewire

Indications for Use *(Describe)*
The X-Wire Guidewire is indicated for general intravascular use within the peripheral and neuro vasculature to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary 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.

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510(k) Summary
K244061

A. Submitter Information:

Submitter's Name:	Imperative Care, Inc.
Address:	1359 Dell Avenue Campbell, CA 95008
Contact Person:	Shivani Patel
Telephone:	510-468-8862
Email:	spatel@imperativecare.com
Date of Preparation:	August 21, 2025

B. Subject Device:

Proprietary Name:	X-Wire Guidewire
Common/Usual Name:	Guidewire
Classification Name:	Catheter guide wire
Product Codes:	MOF, DQX
Regulation:	21 CFR 870.1330
Manufacturer	Imperative Care, Inc.

C. Predicate Devices:

Proprietary Names:	Aristotle 18 Guidewire; Aristotle 24 Guidewire (K231954) Aristotle 14 Guidewire (K220398)
Common/Usual Name:	Guidewire
Classification Name:	Catheter guide wire
Product Codes:	MOF, DQX
Regulation:	21 CFR. 870.1330
Manufacturer:	Scientia Vascular, Inc.

D. Device Description:

The Imperative Care's X-Wire Guidewires are guidewires with shapeable tips to aid in accessing the peripheral and neuro vasculature. The guidewires are available in 200cm - 300cm lengths, standard (S) and support (T) stiffness profiles, and 0.014", 0.018" and 0.024" diameters. The distal portion of the guidewire tip includes a radiopaque marker to facilitate fluoroscopic visualization. A hydrophilic coating on the distal segment and PTFE coating on the proximal segment serve to reduce friction during manipulation in vessels. The X-Wire Guidewire is supplied with a shaping mandrel, introducer, and torque device.

E. Indications for Use:

The X-Wire Guidewire is indicated for general intravascular use within the peripheral and neuro vasculature to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

F. Comparison with the Predicate Devices:

The predicate devices are the Aristotle 18, 24, and 14 Guidewires cleared under K231954 and K220398. The predicate and subject devices share the same intended use and basic technological characteristics as shown in **Table 1**, below.

Table 1: Comparison of Subject and Predicate Devices

	Predicate Aristotle 18 and 24 Guidewires (K231954)	**Predicate Aristotle 14 Guidewire (K220398)**	**Subject Device X-Wire Guidewire (K244061)**
Regulation Number	21 CFR 870.1330	Same	Same
Regulation Name	Catheter Guide Wire	Same	Same
Regulatory Class	Class II	Same	Same
Product Code	MOF, DQX	Same	Same
Manufacturer	Scientia Vascular, Inc.	Scientia Vascular, Inc.	Imperative Care., Inc
Anatomical Location	Peripheral and Neuro Vasculature	Same	Same
Indications for Use	The Aristotle 18 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature. The Aristotle 24 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use	The Aristotle 14 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.	The X-Wire Guidewire is indicated for general intravascular use within the peripheral and neuro vasculature to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

	Predicate Aristotle 18 and 24 Guidewires (K231954)	Predicate Aristotle 14 Guidewire (K220398)	Subject Device X-Wire Guidewire (K244061)
	in the coronary vasculature.		
Condition Supplied	Sterile, single-use	Same	Same
Accessory Devices	Shaping Mandrel, Introducer, Torque Device	Same	Same
Wire Outer Diameter	0.018" (0.46mm) 0.024" (0.61mm)	0.014" (0.36mm)	0.014" (0.36mm) 0.018" (0.46mm) 0.024" (0.61mm)
Device Length	200 cm, 300 cm	200cm, 300cm	X-Wire 14: Same as Aristotle 14 X-Wire 18: 200cm, 260cm, 300cm X-Wire 24: Same as Aristotle 24
Tip Length (Hypotube)	35cm	35cm	X-Wire 14S: 29cm X-Wire 14T: 19cm X-Wire 18S: 35cm X-Wire 18T: 25cm X-Wire 24S: 43.5cm X-Wire 24T: 50cm
Tip Type and Shape	Core-to-tip Shapeable	Same	Same
Flexible Tip Material (Distal Tip)	Nitinol	Same	Same
Core Wire Material	Stainless Steel	Same	Same
Stiffness Profile	Support, Standard, Soft	Soft, Standard	Support, Standard
Coatings	*Distal End:* Hydrophilic *Proximal End*: PTFE	Same	Same
Hydrophilic Coating Length	46cm	46cm	X-Wire 14S: 41cm X-Wire 14T: 27.5cm X-Wire 18S: 50cm X-Wire 18T: 41cm X-Wire 24S: 60cm X-Wire 24T: 60cm

	Predicate Aristotle 18 and 24 Guidewires (K231954)	Predicate Aristotle 14 Guidewire (K220398)	Subject Device X-Wire Guidewire (K244061)
Radiopaque Marker	1 radiopaque marker at distal tip	Same	Same
Radiopaque Length	10cm	10cm	85mm (8.5cm)
Bushing	Aristotle 24: Nitinol Bushing Aristotle 18: None	None	None
Centering Coil	Aristotle 18: 1 centering coil Aristotle 24: 2 centering coils	1 centering coil	X-Wire 14S:1 centering coil X-Wire 14T: 1 centering coil X-Wire 18S: 2 centering coils X-Wire 18T: 1 centering coil X-Wire 24S: 3 centering coils X-Wire 24T: 2 centering coils
Sterilization Method	EO	Same	Same
Sterility Assurance Level	SAL of 10^{-6}	Same	Same
Shelf Life	36 months	4 months	8 months

G. Performance Data - Bench:

Bench testing was completed to evaluate the differences between the subject devices and predicate devices and to ensure the subject device meets the specifications and performs as intended. The test methods were based primarily on the FDA Guidance, "*Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling, Guidance for Industry and Food and Drug Administration Staff,*" issued in October 2019. A summary of the evaluated performance specifications is presented in **Table 2**.

The test results demonstrated that any differences between the subject devices and predicate devices do not significantly impact performance parameters that would negatively affect the safety or effectiveness of the subject devices.

Table 2: Summary of Bench Tests and Performance Specifications

Test Attribute	Specification	Results
Dimensional Verification	All defined guidewire dimensions are within the specified tolerances.	Pass
Visual Inspection	The guidewire shall be free of visual defects when removed from packaging.	Pass
Torqueability	The guidewire shall transmit rotation from the proximal end to the distal tip to allow users to select branches of the vasculature and reach the target location.	Pass
Torque Strength	In the event where the distal end of the guidewire is unable to move/rotate during the procedure, the device shall not fail under expected torsional input.	Pass
Tip Flexibility	The tip of the guidewire shall not cause vessel damage. Tip flexibility is defined by the ability of the tip to buckle when contacting vessel walls. In doing so it reduces the contact pressure to prevent vessel perforation.	Pass
Tensile Strength and Tip Pull	The guidewire shall withstand tensile forces expected in clinical use without breaking.	Pass
Kink Resistance	The guidewire shall be able to traverse through clinically relevant bends without kinking.	Pass
Coating Integrity	The coating shall remain intact during clinical use.	Pass
Coating Lubricity	The coating shall be lubricious to reduce frictional forces to allow for navigation through tortuous anatomy.	Pass
Particulate Evaluation	The guidewire shall not generate particles at a level that is greater than the range generated by the predicate.	Pass
Corrosion Resistance	The guidewire shall not corrode from the time of manufacture through its shelf life.	Pass
Radiopacity	Opacity to x-ray shall allow physicians to visualize guidewire under fluoroscopy.	Pass
Simulated Use	The guidewire must be able to reach anatomical locations and deliver catheters and other interventional devices used in common neurovascular procedures.	Pass

H. Biocompatibility Testing:

Biocompatibility testing was performed on a representative final, finished guidewire to evaluate all direct patient contacting components of the device. This testing was conducted to ensure that the components and raw materials used in the subject X-Wire Guidewires and the manufacturing processes and sterilization processes result in a biocompatible product. Test results and an expert evaluation confirmed that the subject X-Wire Guidewires met biological safety requirements per ISO 10993-1 for externally communicating medical devices with direct circulating blood contact for ≤24 hours.

Table 3: Biocompatibility Test Summary – X-Wire Guidewire

Test	Test Method	Extraction Methods/Conditions	Acceptance Criteria	Results
Cytotoxicity	ISO 10993-5 ISO 10993-12	Test device extracted with MEM with 5% serum at 37°C for 72 hours.	Test article extracts must yield grade 2 or lower.	**Pass, Non-cytotoxic**
Sensitization	ISO 10993-10 ISO 10993-12	Test device extracted with both SC and SO at 50°C for 72 hours.	Overall pattern, intensity, duration, character of reactions compared to control conditions.	**Pass, Non-sensitizer**
Irritation or Intracutaneous Reactivity	ISO 10993-23 ISO 10993-12	Test device extracted with both SC and SO at 50°C for 3 hours.	Difference between test extract mean score and corresponding control mean score ≤1.	**Pass, Non-irritating**
Acute Systemic Toxicity	ISO 10993-11 ISO 10993-12	Test device extracted with both SC and SO at 50°C for 72 hours.	None of the animals treated with the test article extracts must show a significantly greater biological reactivity than animals treated with the control article.	**Pass, Non-toxic (acute systemic)**
Material Mediated Pyrogenicity	ISO 10993-11 USP <151> ISO 10993-12	Test device extracted with SNPS at 50°C for 72 hours.	Test article extract must yield <0.5°C rise of	**Pass, Non-pyrogenic**

Test	Test Method	Extraction Methods/Conditions	Acceptance Criteria	Results
			individual animal baseline temperature.	
Hemocompatibility – Hemolysis (Direct and Indirect Contact)	ISO 10993-4 ASTM F756 ISO 10993-12	Direct Contact: Test device incubated directly in diluted blood at 37°C for 72 hours. Indirect Contact: Test device extracted in CMF-PBS at 50°C for 72 hours and then extracts incubated with diluted blood at 37ºC for 3 hours.	Test article extract must result in hemolytic index of <2%.	**Pass, Non-hemolytic for both Direct and Extract Methods**
Hemocompatibility - SC5b-9 Complement Activation	ISO 10993-4	Test device exposed to Normal Human Serum at 37°C for 60 minutes.	SC5b-9 concentration of the test article is similar to both the activated NHS and negative controls.	**Pass, Hemocompatible**
Hemocompatibility – I*n vivo* thromboresistance	ISO 10993-4	N/A, non-anticoagulated venous implant study.	Test article performs similarly to the predicate.	**Pass, Hemocompatible**

I. Sterilization:

The X-Wire Guidewires are sterilized using a validated EO process with a sterility assurance level of $1x10^{-6}$ validated per the overkill method in accordance with ISO 11135, "Sterilization of Health-Care Products - Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices".

J. Shelf Life and Packaging:

Accelerated aging testing based on ASTM F1980 was conducted to verify device, accessory, and packaging performance. An accelerated aging equivalent of 8 months was used to support 8-month shelf life. Device performance was verified by functional and performance testing.

Packaging and sterile barrier integrity through transportation challenge has been verified. Aging testing has also been performed that supports the sterile barrier integrity following 8 months of accelerated aging.

K. Animal Study:

Animal study was not deemed necessary to demonstrate substantial equivalence.

L. Clinical Study:

Clinical study was not deemed necessary to demonstrate substantial equivalence.

M. Conclusions:

The X-Wire Guidewire has the same intended use and similar technological characteristics as the predicate devices. The performance testing was conducted to ensure the subject device performs as intended, meets all design specifications, and performs consistently throughout its labeled shelf life. The differences between subject and predicate devices do not raise any new or different questions of safety and effectiveness. Therefore, the X-Wire Guidewire is substantially equivalent to the predicate devices.