September 18, 2024

Teleflex Medical
Madison Snyder
Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K241784
Trade/Device Name: Arrow® Nitinol Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 25, 2024
Received: June 20, 2024

Dear Madison Snyder:

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2024.09.18 16:36:15 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241784

Device Name
Arrow® Nitinol Wire

Indications for Use *(Describe)*
The Arrow® Nitinol Wires are intended to facilitate the placement of central circulatory system or peripheral vasculature devices for diagnostic and interventional 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY
Arrow® Nitinol Wire
K241784

Name, Address, Phone and Fax Number of Applicant

Arrow International LLC
Subsidiary of Teleflex Incorporated
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 919.433.4932
Fax: 919.433.4996

Contact Person

Madison Snyder
madison.snyder@teleflex.com
Regulatory Affairs Specialist

Date Prepared

June 13, 2024

Device Name

Device Trade Name: Arrow® Nitinol Wire
Device Common Name: Catheter Guide Wire
Device Classification Name: Wire, Guide, Catheter
FDA Classification Regulation: 21 CFR 870.1330
FDA Classification: Class II
FDA Product Code: DQX
Classification Panel: Cardiovascular
FDA Panel Number: 74

Predicate Device

K142393	Predicate™ III Guidewire (Lake Region Medical)

Device Description

The Arrow® Nitinol Wires are composed of a coil wire wrapped around a solid core wire, designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel to ensure proper tip placement of the catheter. The clinical benefit of the Arrow® Nitinol Wire is allow the clinician the ability to guide and control the advancing movement of the catheter body through the vessel gaining access to the

vascular system through a single puncture site. The guidewires in Arrow / Teleflex Vascular finished goods are typically provided as Spring Wire Guide assemblies including additional components (straightener, Arrow Advancer, tubing clamps, snubber) for easier handling.

The guidewire family is bound by the following parameters:

Core Material	Nitinol
Coil Material	Stainless Steel
Coil length	Full length
Joining Agent	Weld
Tip Type	Straight or J-shaped
Overall Lengths	30cm to 68cm
Overall Diameters	0.018" to 0.035"
Sterilization Method	Ethylene Oxide

Intended Use Statement

The Arrow Nitinol Wires are intended to facilitate the placement of central circulatory system or peripheral vasculature devices for diagnostic and interventional procedures.

Patient Population

The guidewires are intended for use in patients undergoing central or peripheral vascular access procedures where use of a guidewire to aid insertion is indicated. There are no restrictions on the target patient population. Guidewire choice is per clinician expertise and consideration of guidewire size and patient habitus.

Environment of use

The device is to be used in a hospital and sub-acute facility environment as directed by a physician.

Contraindications

There are no known contraindications for this device.

Substantial Equivalence

The proposed device is substantially equivalent to the predicate device:

Predicate Device	Manufacturer	510(k) Number	Date Cleared
PREDICATE III GUIDEWIRE	Lake Region Medical	K142393	November 25, 2014

Comparison to Predicate Device

The proposed device has the same or equivalent indications for use, operating principles, classification, sterilization and general design as the predicate device. The subject and predicate devices are both intended to introduce and place vascular devices. In this

application, the words "coronary vasculature" used for the predicate device means the same as "central circulatory system" used for the subject device. The guidewire is designed for peripheral applications and does not navigate beyond the superior vena cava into further coronary vasculature. Biocompatibility testing and performance testing has been performed on the proposed device in order to establish substantial equivalence to the predicate device. The proposed changes below do not impact the safety or effectiveness of the Arrow Nitinol Wire. The subject device is therefore substantially equivalent to the predicate device identified within this submission.

	Predicate Device K142393 Predicate III Guidewire	**Proposed Arrow Nitinol Wire**	**Equivalence**
Classification Name	wire, guide, catheter	wire, guide, catheter	Identical
Common Name	CATHETER GUIDEWIRE	CATHETER GUIDEWIRE	Identical
Product Code	DQX	DQX	Identical
Classification	Class II	Class II	Identical
Regulation Number	870.1330	870.1330	Identical
Indications for Use	PREDICATE III GUIDEWIRE are indicated to facilitate the placement of devices in angiographic procedures	The Arrow Nitinol Wires are indicated to facilitate the placement of devices for diagnostic and interventional procedures.	EQUIVALENT
Intended Use	The guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature	The guidewires are intended to facilitate the placement of central circulatory system or peripheral vascular devices for diagnostic and interventional procedures.	EQUIVALENT
Device Use	Single Use	Single Use	Identical
Prescription	Yes	Yes	Identical
Contraindications	There are no known contraindications for this device	There are no known contraindications for this device	Identical
Shelf Life	36 months from date of manufacture	60 months from date of manufacture	Similar*
Design	A solid nitinol core wire welded at both ends to SS coil.	A solid nitinol core wire welded at both ends to SS coil	Identical
Tip Type	J-end, straight	J-end, straight	Identical
Coating	None	None	Identical

Core Material	NiTinol	NiTinol	Identical
Coil Material	Stainless steel	Stainless steel	Identical
Diameter	0.018” to 0.038”	0.018" - 0.035” (0.46 – 0.89 mm)	EQUIVALENT
Length	30cm to 500cm	17-3/4" - 23-5/8" (45 – 68 cm)	EQUIVALENT
Biocompatibility	Biocompatible materials used (per ISO 10993-1)	Biocompatible materials used (per ISO 10993-1)	Identical
Sterilization Method	EO	EO	Identical

*Shelf life was established via performance testing of accelerated-aged products.

Materials

All patient contacting materials, including those with indirect patient contact, are in compliance with ISO 10993-1. Biocompatibility testing has been performed on the proposed device and meets the acceptance criteria.

Test	Acceptance Criteria	Result
Cytotoxicity – L 929 Proliferation	The test article will meet the requirements of the test if it obtains a Grade of 0,1,or 2 (not more than 50% of the cells are round, devoid of intracytoplasmic granules, and no extensive cell lysis)	Acceptable
Sensitization – Kligman Maximization Assay	The test article will be considered a non-irritant if the difference between the test article mean score and the vehicle control mean score is 1.0 or less.	Acceptable
Intracutaneous Reactivity Test (Polar and Non- Polar (ISO)	The test article will meet the requirements of the test if it receives a Grade of 1, 0 or less using the Kligman scoring system.	Acceptable
Acute Systemic Toxicity - Systemic Injection Test	The test article will meet the requirements of the test if it does not induce a significantly greater biological reaction than the control.	Acceptable
Acute Systemic Toxicity – Material Mediated Test	The test article will meet the requirements of the test if no rabbit shows an individual rise in temperature of 0.5oC or more above the baseline temperature.	Acceptable

Hemocompatibility – Rabbit Blood Hemolysis (Complete) ASTM Test	The test article will meet the requirements of the test and is not considered to have hemolytic activity potential, if the hemolytic index above the negative control article and negative control article extract is <5%.	Acceptable

Performance Data

Non-clinical performance testing has been conducted in order to support that the proposed device performs as intended and the product conforms to user needs.

Test	Acceptance Criteria	Result
Dimensional Verification	All dimensions shall be statistically inside tolerance limits according to the drawing with assurance of 95%.	Pass
Title: Visual Inspection / Surface	When examined by normal or corrected-to-normal vision with minimum 2.5x magnification, the external surface of the effective length of the device shall appear free from extraneous matter.	Pass
Tensile Strength / Peak Tensile Force	When tested in accordance with the method given in BS EN ISO 11070, Annex H, the minimum peak tensile force of the guidewire and any critical junctions shall be • 2 N for diameters <0.55mm (0.022") • 5 N for diameters ≥0.55mm (0.022") - <0.75 mm (0.030") • 10 N for spring wire guides with diameter ≥0.75 mm (0.030").	Pass
Tip Pull	When tested in accordance with the method given in BS EN ISO 11070, Annex H, the minimum peak tensile force of the guidewire and any critical junctions shall be • 2 N for diameters <0.55mm (0.022") • 5 N for diameters ≥0.55mm (0.022") - <0.75 mm (0.030") • 10 N for spring wire guides with diameter ≥0.75 mm (0.030").	Pass
Torque Strength	Torque strength of subject device is substantially equivalent to the predicate device.	Pass
Corrosion Resistance	When tested in accordance with the method given in BS EN ISO 11070, Annex B, metallic components of the device shall show no visible signs of corrosion that can affect functional performance or biocompatibility test results.	Pass

Kink Resistance	Fracture test: When tested in accordance with BS EN ISO 11070, Annex F, the spring wire guide shall not fracture, loosen, or fail in such a manner that a. any section of the coil is left free to stretch b. a sharp, or potentially traumatic fracture surface is exposed, or c. any part of the device becomes separated such that it would not be removable by withdrawing the device from use. Flexing test: When tested in accordance with BS EN ISO 11070, Annex G, Neither the distal end of the guide wire nor the remaining portion of the guide wire shall show signs of defects or damage. Kink Resistance Test: Characterization and comparison with predicate device. Test samples after being subjected to the test with pin gauge of particular radius did not show worse kink or plastic deformation or/and fracture compared to the predicate device.	Pass
Tip Flexibility	The tip shall visually exhibit higher flexibility than the rest of the wire.	Pass
Radiopacity	The spring wire guide has to be clearly visible on X-ray picture in its full length despite of shadowing by the water tank or human body.	Pass

Conclusion

Based on the performance and comparative test results, the proposed Arrow Nitinol Wire is substantially equivalent to the predicate device cleared to market in K142393 The modifications made to the Nitinol Wire do not introduce any new issues of safety and effectiveness.