February 13, 2026

Abbott Medical
Daire Farrell
Senior Specialist Regulatory Affairs
3200 Lakeside Dr.
Santa Clara, California 95054

Re: K252512
Trade/Device Name: Armada™ 14 NC PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: January 20, 2026
Received: January 20, 2026

Dear Daire Farrell:

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 13484 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 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 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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2026.02.13 08:01:16 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
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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)*
K252512

Device Name
Armada™ 14 NC PTA Catheter

Indications for Use *(Describe)*
The Armada™ 14 NC PTA Catheter is indicated to dilate stenosis in the peripheral vasculature, including femoral, infra-popliteal, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The 2.0 mm to 6.0 mm balloon diameters are also indicated for post-dilatation of balloon-expandable stents, scaffolds (i.e., the Abbott Esprit™ BTK Everolimus Eluting Resorbable Scaffold System), and self-expanding stents in the peripheral 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
Per 21 CFR §807.92

510(k) Number	K252512
Date Prepared	February 12, 2026
Submitter Name & Address	Abbott Medical 3200 Lakeside Drive Santa Clara, CA 95054
Contact Person	Daire Farrell
Proprietary / Trade Name	Armada™ 14 NC PTA Catheter
Common / Usual Name	Catheter, Angioplasty, Peripheral, Transluminal
Product Classification	Class II
Product Code	LIT
Product Regulation Number	21 CFR 870.1250
Predicate Device	Armada™ 14 PTA Catheter (K102705)
Additional Predicate & Reference Devices	• Armada™ 18 PTA Catheter (K151317) • NC Trek Neo PTCA Catheter (K220634) • NC TREK OTW and TREK OTW/MINI TREK OTW (K180040)

Device Description

Armada 14 NC is a Non-Compliant (NC), Over The Wire (OTW), Percutaneous Transluminal Angioplasty (PTA) Catheter with a balloon located near the distal atraumatic tip. The single layer Nylon (1.50 mm to 2.50 mm) and multi-layer (Pebax / Nylon) (3.00 mm to 6.00 mm) balloons are available in the following nominal diameters: 1.50, 2.00, 2.50, 3.00, 3.50, 3.75, 4.00, 4.25, 4.50, 5.00, 5.50 and 6.00 mm across a range of lengths 10, 20, 30, 40, 60, 80, 100, 120 and 150mm. The device consists of an outer lumen which provides for inflation of the balloon with contrast medium and the inner lumen which permits a guidewire to facilitate advancement of the catheter. The balloon and outer member are coated with Hydrophobic coating.

Indications for Use

The Armada™ 14 NC PTA Catheter is indicated to dilate stenosis in the peripheral vasculature, including femoral, infra-popliteal, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The 2.0 mm to 6.0 mm balloon diameters are also indicated for post-dilatation of balloon-expandable stents, scaffolds

(i.e., the Abbott Esprit™ BTK Everolimus Eluting Resorbable Scaffold System), and self-expanding stents in the peripheral vasculature.

Comparison of Subject to Predicate Device

The intended use is identical between the subject and predicate devices. The indications for use differ in that the subject device is also indicated for post-dilatation of vascular scaffolds. Non-clinical testing is sufficient to demonstrate substantial equivalence for this indication.

The subject device and predicates have similar functional specifications, materials, and design. The subject device has design modifications including a non-compliant balloon and a dual material layer balloon for select balloon diameters (i.e., 3.00-6.00mm). Non-clinical testing was sufficient to demonstrate substantial equivalence of the subject and predicate devices despite these differences.

Summary of Non-Clinical Testing

The safety and effectiveness of the Armada™ 14 NC PTA Catheter was evaluated through bench testing and simulated use testing. The test results demonstrate that the Armada™ 14 NC PTA Catheter meets the acceptance criteria of functional, dimensional, and simulated use testing.

The following verification and validation testing were completed:

- Dimensional Inspection:
    - Tip Length
    - Tip Entry Diameter
    - Crossing Profile
    - Guidewire Lumen Dimensions
    - Balloon Shoulder to Balloon Marker Alignment
    - Balloon Dimensions: Balloon Working Length
    - Proximal Shaft Profile
    - Distal Shaft Profile
    - Total Catheter Length
- Catheter Preparation
- Balloon Deflation Time
- Balloon Inflation Time
- Balloon Rated Burst Pressure
- Balloon Maximum Compliance Label
- Balloon Outer Diameter at Nominal Pressure
- Balloon Rated Burst Pressure (In-Stent)
- Luer Bond Tensile Strength
- Proximal Seal Tensile Strength
- Catheter Tip Tensile Strength
- Inner Member Lumen Collapse Pressure
- Balloon Fatigue Resistance
- Balloon Fatigue Resistance (In-Stent)
- Hydrophobic Coating: Coefficient of Friction

- Kink/Flex
- Torque
- Particulates
- Contamination Index for Particulates
- Simulated Use

A biocompatibility evaluation was conducted in accordance with the ISO 10993-1 (2018): Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process, and the FDA Guidance (2023): Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1 Evaluation and testing within a risk management process". The assessment considered the device's materials, manufacturing processes, and clinical use, demonstrating chemical and physical equivalence to predicate and reference devices. Based on this evaluation and data on equivalent devices the subject device presents no new biocompatibility risks. Therefore, no additional testing is required, and the device is considered biocompatible for its intended use.

Summary of Clinical Testing

Clinical studies were not needed to support substantial equivalence between subject and predicate devices.

Statement of Substantial Equivalence

The intended use is identical between the subject and predicate devices. The subject and the predicate devices have equivalent indications for use. The subject and the predicate devices have equivalent technological characteristics including functional specifications, materials and design. Differences in subject and predicate device indications for use and technological characteristics do not raise any different questions of safety and effectiveness. A biocompatibility assessment has been completed to demonstrate substantially equivalent safety between subject and predicate devices. The results from performance testing, which included non-clinical bench testing and simulated use testing, demonstrated that the Armada™ 14 NC PTA Catheter met all acceptance criteria to demonstrate substantially equivalent safety and effectiveness between subject and predicate devices.