April 6, 2022

Dunia Bram
Principal Specialist, Regulatory Affairs
14201 N.W. 60th Avenue
Miami Lakes, Florida 33014

Re: K220654
Trade/Device Name: ANGIOGUARD XP Emboli Capture Guidewire, ANGIOGUARD RX Emboli Capture Guidewire
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: March 4, 2022
Received: March 7, 2022

Dear Dunia Bram:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Finn Donaldson
Acting 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)*
K220654

Device Name
ANGIOGUARD XP and ANGIOGUARD RX Emboli Capture Guidewire

Indications for Use *(Describe)*
ANGIOGUARD XP and ANGIOGUARD RX Emboli Capture Guidewire devices are indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3mm to 7.5mm.

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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I. SUBMITTER

Cordis US Corporation
14201 N.W. 60th AVE.
Miami Lakes, FL 33014, USA
Phone: (408) 273-3423
Fax: (408) 955-0704
Establishment registration number: 1016427

Contact:
Dunia Bram
Cordis US Corp.
Date Prepared: March 4, 2022

II. DEVICE

Trade Name: ANGIOGUARD® XP Emboli Capture Guidewire
ANGIOGUARD® RX Emboli Capture Guidewire

Common Name: Embolic Protection Guidewire

Classification Name: Cardiovascular Percutaneous Catheter and Catheter Guidewire

Device Classification: 21 CFR §870.1250 and 21 CFR §870.1330

Regulatory Class: Class II

Product Code: NTE – temporary carotid catheter for embolic capture

III. PREDICATE DEVICE

ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire, previously cleared under K101651 on July 9, 2010, and under K062531 on September 22, 2006.

IV. DEVICE DESCRIPTION

Both the subject and predicate ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire devices consists of a guidewire with integrated emboli filter basket at the distal end. The devices function as an interventional guidewire and distal protection device during delivery and placement of stents and interventional devices in carotid procedures. The guidewire is delivered via an OTW (over-the-wire) or RX (rapid-exchange) deployment sheath and is captured via an OTW or RX capture sheath. The ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire devices have a filter basket at the distal end that is deployed prior to the stenting procedure. When deployed, the filter basket opens in an umbrella-like

fashion, allowing passive hemo-filtration with subsequent emboli capture. At the end of the procedure, the filter is collapsed and retrieved.

V. INDICATIONS FOR USE

ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire devices are indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3mm to 7.5mm.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire are identical in its basic design, intended use, indications for use statement, contraindications, mechanism of action, operating principle, sterilization method and Sterility Assurance Level (SAL). The changes to the subject device relative to the predicate are limited to a material change for the Deployment and Capture Sheath components.

With the exception of the Deployment Sheath and Capture Sheath material change, the subject and predicate devices share the same materials, design, dimensions, size range, intended use, principle of operation, mechanism of action, method of sterilization and sterility assurance level, biocompatibility classification, labeling, packaging materials and configuration, and shelf life. The new material for the Deployment Sheath and Capture Sheath meets the same requirements as the current material.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing

Biocompatibility testing was performed on finished and sterilized ANGIOGUARD XP and ANGIOGUARD RX Emboli Capture Guidewire in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR Part 58 and per International Standard ISO 10993-1:2018 and FDA guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", September 2020.
Biocompatibility testing performed included the following:

- Chemical Characterization
- Cytotoxicity – MEM Elution
- Sensitization – Guinea Pig Maximization
- Intracutaneous Irritation Reactivity
- Acute Systemic Toxicity

- Material Mediated Pyrogenicity
- Hemocompatibility
    - Hemolysis – Extract & Direct Contact
    - Platelet and Leukocyte Count
    - Partial Thromboplastin Time
    - Complete Activation Assay
    - Thrombin Antithrombin Assay (TAT)
    - In Vitro Blood Loop Assay

Bench Testing

- Visual inspection
- Dimensional verification
- Deployment and Capture Sheath Tensile Test
- Material evaluation
    - Fourier Transform Infrared Spectroscopy (FTIR)
    - Differential Scanning Calorimetry (DSC)
    - Scanning Electron Microscopy (SEM) / Elemental Analysis (EDAX)

VIII. CONCLUSIONS

The subject ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire are the same in basic design and have the same intended use as the legally marketed predicate, ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire. The modifications made to the Deployment and Capture Sheath material do not alter the fundamental scientific technology of the device, the device's operating principles, mechanism of action, intended use, or the indication for use of the device. The material modification made to the ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire were verified and validated through a series of tests ensuring that the subject guidewire meets all specifications and that the performance and functionality are substantially equivalent to the predicate device. The ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire continues to meet all previous performance specifications and none of the critical clinical performance parameters have changed. The modifications do not raise new questions of safety and effectiveness. ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire can be used according to its intended use and in an equivalent manner to the predicate device. The subject ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire devices are substantially equivalent to the predicate ANGIOGUARD XP Emboli Capture Guidewire and ANGIOGUARD RX Emboli Capture Guidewire devices.