June 28, 2024

Cordis US Corp.
Linda Ruedy
Senior Director, Global Regulatory Affairs
14201 NorthWest 60th Avenue
Miami Lakes, Florida 33014

Re: K233637
Trade/Device Name: Cordis BRITECROSS Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 13, 2023
Received: November 13, 2023

Dear Linda Ruedy:

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.

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,

Samuel G. Raben -S

for 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)*
K233637

Device Name
Cordis BRITECROSS Support Catheter

Indications for Use *(Describe)*
The Cordis BRITECROSS Support Catheters are indicated to guide and support a guide wire during access to the peripheral vasculature, allow for exchange of guide wires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

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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Cordis

Traditional 510(k)

BRITECROSS™ Support Catheter

510(K) SUMMARY

Sponsor/Submitter: Cordis US Corp
14201 North West 60th Avenue
Miami Lakes, Florida 33014, USA

Contact Person: Linda Ruedy
Senior Director, Global Regulatory Affairs
Phone: (408) 857-6754

Date Prepared: November 09, 2023

Device Trade Name: Cordis BRITECROSS™ Support Catheter

Common Name: Peripheral Support Catheter

Device Classification: Class II

Regulation Number: 21 CFR 870.1250

Classification Name: Catheter, Percutaneous

Product Code: DQY

Predicate Device: Spectranetics Quick-Cross Support Catheters (K072750)

Device Description: The BRITECROSS Support Catheter is a flexible single lumen catheter that is intended to cross lesions to facilitate guidewire access and/or the delivery of saline/contrast during peripheral vascular interventions. The subject device is designed to allow for fluoroscopic visualization of the catheter. The radiopaque distal tip allows for accurate placement of the tip relative to the lesion. Further, there are two (2) radiopaque marker bands incorporated along the shaft to provide the clinician with a length reference facilitating approximation of the lesion length. On the proximal end, the hub has an integrated strain relief and a standard female luer to connect with a standard syringe. The BRITECROSS Catheter is available in various lengths and diameters and the size is printed on the hub for quick identification. The device is sterile and is for single use.

Device Operation:

Through a previously inserted guide catheter or introducer sheath, the clinician introduces the BRITECROSS Support Catheter over the guidewire and advances the subject device under fluoroscopy to the desired location within the vasculature in the peripheral vessels. The radiopaque distal tip and two (2) marker bands allow for the clinician to visualize the distal end of the subject device as well as provide an approximation of lesion length. The BRITECROSS Catheter facilitates guidewire exchange and allows for infusion of either sterile saline or contrast.

Indications for Use:

The Cordis BRITECROSS Support Catheters are indicated to guide and support a guide wire during access to the peripheral vasculature, allow for exchange of guide wires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Technological Characteristics:

The BRITECROSS Support Catheter can be introduced over the guidewire and advanced under fluoroscopy to the desired location within the vasculature and navigating tortuous anatomy in the peripheral vessels. The radiopaque distal tip and two (2) radiopaque marker bands allow for the clinician to visualize the distal end of the subject device as well as provide an approximation of lesion length. The BRITECROSS Catheter facilitates guidewire exchange and allows for infusion of either sterile saline or contrast at specified injection pressures.

Performance Data:

The function of the BRITECROSS Support Catheter has been verified through:

- Performance Testing (dimensional, mechanical, *in-vitro* testing)
    - Dimensional measurements
    - Kink test testing
    - 3-point bend testing
    - Tensile strength testing
    - Leak testing
    - Bend failure testing
    - Hydrophilic coating length
    - Coating friction
    - Torque testing
    - Coating integrity testing
    - Particulate testing
    - Trackability testing
    - Ability to deliver fluids
- Biocompatibility (ISO 10993-1)
    - Cytotoxicity
    - Irritation
    - Sensitization
    - Acute systemic toxicity
    - Material mediated pyrogen
    - Hemolysis
    - Hemocompatibility
- Sterilization (ISO 11137-1)

Cordis

Traditional 510(k)

BRITECROSS™ Support Catheter

Clinical Data: No clinical data was required.

Animal Data: No animal performance data was required.

Predicate Device Comparison

Attribute	Subject Device Cordis BRITECROSS™ Support Catheter	Primary Predicate Device Spectranetics Quick-Cross Support Catheter	Reference Device Terumo Medical R2P Navicross
510(k) number	TBD	K072750	K231044
Clearance Date	TBD	December 4, 2007	July 27, 2023

Attribute	Subject Device Cordis BRITECROSS™ Support Catheter	Primary Predicate Device Spectranetics Quick-Cross Support Catheter	Reference Device Terumo Medical R2P Navicross
Manufacturer	Cordis US Corp	Spectranetics Corp	Terumo Medical
Trade Name	BRITECROSS™ Support Catheter	Quick-Cross Support Catheter	Navicross Support Catheter
Common Name	Support Catheter	Same, Support Catheter	Same, Support Catheter
Class	II	Same, II	Same, II
Product Code	DQY	Same, DQY	Same, DQY
Classification Section	870.1250	Same, 870.1250	Same, 870.1250
Indications for Use	Indicated to guide and support a guide wire during access to the peripheral vasculature, allow for exchange of guide wires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.	Intended to support a guide wire during access to the vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.	Indicated to guide and support a guidewire during access of the peripheral vasculature through an access site, including but not limited to the radial artery, allow for wire exchanges, and provide a conduit for the delivery of saline or diagnostic contrast agents
Intended Region	Peripheral Vasculature	Same, Peripheral Vasculature	Same, Peripheral Vasculature
Intended Use	To support guide wire access and deliver saline and/or contrast	Same, To support guide wire access and deliver saline and/or contrast	Same, To support guide wire access and deliver saline and/or contrast
Operating Principle	Manual	Same, Manual	Same, Manual
Technological Characteristics	Flexible catheter with lubricious coating, radiopaque markers, and hub	Same, Flexible catheter with lubricious coating, radiopaque markers, and hub	Same, Flexible catheter with lubricious coating, radiopaque markers, and hub
Anatomical Access	Peripheral Vasculature	Same, Peripheral Vasculature	Same, Peripheral Vasculature
Single Use?	Yes	Same, Yes	Same, Yes
Provided Sterile?	Yes	Same, Yes	Same, Yes
Guidewire Compatibility	014”, 018”, and 035”	Same, 014”, 018”, and 035”	Same, 014”, 018”, and 035”
Effective Lengths (cm)	65, 90, 135, 150, 190, 200	Same 014”: 135, 150 018”: 90, 135, 150 035”: 65, 90, 135, 150	Same, 200
# Radiopaque Markers	3 (including tip)	Same, 3	Same, 3

Attribute	Subject Device Cordis BRITECROSS™ Support Catheter	Primary Predicate Device Spectranetics Quick-Cross Support Catheter	Reference Device Terumo Medical R2P Navicross
Marker Spacing (mm)	014: 15mm 018: 15mm 035: 50mm	Same, 014: 15mm 018: 15mm 035: 50mm	40mm, 60mm
Sheath Compatibility	4F, 5F	Same, 4F, 5F	4.5F
Single Lumen?	Yes	Same, Yes	Same, Yes
Maximum Injection Pressure	300psi	Same, 300psi	600psi

Summary of Substantial Equivalence: The Cordis BRITECROSS Support Catheter is substantially equivalent to the predicate device as confirmed through relevant performance tests and attributes.