DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 19, 2015

Cordis Corporation, a Johnson & Johnson Company
Michelle Ragozzino Rodgers, Ph.D.
Senior Regulatory Affairs Specialist
6500 Paseo Padre Parkway
Fremont, California 94555

Re: K150187
Trade/Device Name: ELITECROSS Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: April 13, 2015
Received: April 14, 2015

Dear Dr. Rodgers:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150187

Device Name
ELITECROSS™ Support Catheter

Indications for Use *(Describe)*
The Cordis ELITECROSS™ Support Catheter is intended to facilitate the intraluminal placement of diagnostic/ interventional devices beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention, and to deliver saline or contrast medium. Additionally, ELITECROSS™ can be used as an accessory with the FRONTRUNNER® XP CTO Catheter.

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

I. SUBMITTER

Cordis Corporation
6500 Paseo Padre Parkway
Fremont, CA 94555

Contact Person: Michelle Ragozzino Rodgers, Ph.D.
Tel: (510) 248-2450
Fax: (510) 248-2533

Date Prepared: January 23, 2015

II. DEVICE

Name of Device: ELITECROSS™ Support Catheter
Common Name: Percutaneous catheter
Classification Name: Catheter for Crossing Total Occlusions (21 CFR §870.1250)
Regulatory Class: Class II
Product Code: PDU

III. PREDICATE DEVICE

Primary Predicate:
Cordis Micro Guide Catheter ELITE, previously cleared on 11/14/2014 under K140438.
Regulation Number: 21 CFR §870.1250. Product Code: PDU
This predicate has not been the subject of a recall.

Reference Device:
Cook CXI Support Catheter (K122796)
Regulation Number: 21 CFR §870.1210
Product Code: KRA

IV. DEVICE DESCRIPTION

The ELITECROSS™ Support Catheter is a single-use, 5F sheath-compatible sterile catheter designed to provide additional support to the distal portion of ancillary diagnostic/interventional devices, including the FRONTRUNNER® XP CTO Catheter, as well as to deliver saline or contrast medium. After crossing the occlusion with the ancillary device, the ELITECROSS™ may be used to facilitate placing a guide wire across the occlusion.

The ELITECROSS™ Support Catheter device is a single lumen torqueable tube containing a full-length PTFE inner liner that is surrounded by a stainless steel braid, which is further encompassed by a polymer jacket, and features a final external hydrophilic coating on the distal 40 cm of the catheter body. The proximal end utilizes a molded hub with a luer fitting for flushing, with winged tabs designed to facilitate maneuvering and torqueing in the vasculature, while the distal tip contains a radiopaque marker band for visibility under fluoroscopy. The ELITECROSS™ Support Catheter will be available in various configurations and several

lengths. The ELITECROSS™ Support Catheter is provided sterile (by EO) and intended for single use only.

V. INDICATIONS FOR USE

The Cordis ELITECROSS™ Support Catheter is intended to facilitate the intraluminal placement of diagnostic/interventional devices beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention, and to deliver saline or contrast medium. Additionally, ELITECROSS™ can be used as an accessory with the FRONTRUNNER® XP CTO Catheter.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject ELITECROSS™ Support Catheter device is identical to the predicate Micro Guide Catheter ELITE with respect to intended use, design, materials, dimensions, configurations, operating principle, control mechanism, and site of manufacture of the device. The subject and predicate devices are based on the following same technological elements:

- Catheter—Facilitates placement of and provides support to ancillary diagnostic/interventional devices, including Frontrunner® XP CTO Catheter
- Single lumen torqueable tube containing a full-length PTFE inner liner that is surrounded by a stainless steel braid, which is further encompassed by a polymer jacket
- Use of hydrophilic coating for distal lubricity to advance through lesion
- Use of marker bands and radiopaque materials for fluoroscopic visualization of catheter tip
- Use of a standard male luer fitting for flush port
- EO sterilized, single use device

Relative to the predicate, changes are limited to the labeling of ELITECROSS™ Support Catheter, including the trade name, labeled sheath compatibility (with no dimensional changes to the device), and edits to the Indications for Use statement (with no change to the Intended Use of the device). Additional testing supported the labeling of ELITECROSS for 5F Catheter Sheath Introducer (CSI) compatibility, with no dimensional changes to the subject device relative to the predicate. The labeling of ELITECROSS for the delivery of saline or contrast was supported by verification and validation activities, risk analyses, and similarities to the cleared reference device. The labeling modifications do not raise new questions of safety and effectiveness.

VII. PERFORMANCE DATA

Device Dimensional and Functional Testing

- Catheter Sheath Introducer (CSI) Compatibility
- Static Burst Testing
- Flow Rate Performance Testing

VIII. CONCLUSIONS

The subject ELITECROSS Support™ Catheter has the same design and intended use as the predicate, Micro Guide Catheter ELITE. The labeling modifications to the ELITECROSS™ product family do not alter the fundamental scientific technology, operating principles, mechanism of action, or intended use of device. Design verification and validation testing demonstrate that the ELITECROSS™ Support Catheter meets applicable performance requirements. The labeling modifications do not raise new questions of safety and effectiveness. The ELITECROSS™ continues to meet all previous performance specifications for Micro Guide Catheter ELITE, and none of the critical clinical performance parameters have changed. ELITECROSS Support™ Catheter can be used according to its intended use and in an equivalent manner to the predicate device.