January 11, 2018

Cook Incorporated
Daniel Corbin
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K183467
Trade/Device Name: Roadrunner Extra Support Wire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 13, 2018
Received: December 14, 2018

Dear Daniel Corbin:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael John -S
2019.01.11 15:18:36 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183467

Device Name
Roadrunner® Extra Support Wire Guide

Indications for Use *(Describe)*
The Roadrunner Extra Support Wire Guide is intended for use in facilitating delivery of percutaneous catheters into the cardiovascular system.

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

Submitted By: Daniel J. Corbin
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (812) 335-3575 x104018
Fax: (812) 332-0281
Date Prepared: December 13, 2018

Device:

Trade Name:	Roadrunner® Extra Support Wire Guide
Common Name:	Wire, Guide, Catheter
Classification Name:	Catheter guide wire DQX (21 CFR §870.1330)

Indications for Use:

The Roadrunner® Extra Support Wire Guide is intended for use in facilitating delivery of percutaneous catheters into the cardiovascular system.

Predicate Device:

The device, subject of this submission, is substantially equivalent to the predicate device, the Roadrunner® Extra Support Wire Guide, cleared under 510(k) number K171948.

Comparison to Predicate Device:

It has been demonstrated that the subject device, Roadrunner® Extra Support Wire Guide, is a modification to the predicate device. The subject device, Roadrunner® Extra Support Wire Guide is identical in terms of intended use, principles of operation, materials of construction, and basic technological characteristics to the predicate device. The predicate device, K171948, is available with an outer diameter of 0.014 inch and lengths of 180 and 300 centimeters and the subject device, the Roadrunner® Extra Support Wire Guide, is available with an outer diameter of 0.018 inch and lengths of 180, 270, and 300 centimeters.

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Device Description:

The Roadrunner® Extra Support Wire Guide is manufactured in an outer diameter of 0.018 inch and lengths of 180, 270, and 300 centimeters. The flexible tip portion of the subject device is formed into an angled configuration. The Roadrunner® Extra Support Wire Guide consists of a coated mandril with a coil covering the tip of the mandril. A pin vise is supplied with the subject device.

The Roadrunner® Extra Support Wire Guide is a packaged, sterile device intended for single use.

Test Data:

The following tests were performed to demonstrate that the Roadrunner® Extra Support Wire Guide met applicable design and performance requirements and support a determination of substantial equivalence.

- Immersion Corrosion Testing – Testing demonstrated, when tested in accordance with Annex B of BS EN ISO 11070:2014, the device revealed no signs of corrosion that would affect functional performance. The pre-determined acceptance criteria were met.
- Surface Condition/Analysis Testing – Characterization testing was performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).
- Flex Testing – Testing was performed in accordance with Annex G of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Fracture Testing – Testing was performed in accordance with Annex F of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Tensile Testing – Testing was performed in accordance with Annex H of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Radiopacity Testing – Radiopacity testing was performed in accordance with the qualitative evaluation described in ASTM F640-12.

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- Rotational Response (Torqueability) Testing – Characterization testing was performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).

- Torque Strength Testing – Characterization testing was performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).

- Compatibility Testing – Testing was performed in accordance with the FDA Guidance for Coronary and Cerebrovascular Guidewires (1995). The pre-determined acceptance criteria were met.

- Dimensional Analysis Testing – Testing was performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995). The pre-determined acceptance criteria were met.

- Flex Testing on Aged Devices – Flex testing was performed on aged devices in accordance with Section 8.5 and Annex B of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.

In conclusion, the results of these tests support a determination of substantial equivalence to the predicate device.