January 5, 2018

Cook Incorporated
Ms. Jennifer Allman
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47402

Re: K171948
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 6, 2017
Received: December 7, 2017

Dear Ms. Allman:

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.

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.

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,

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)*
K171948

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Submitted By: Jennifer L. Allman
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (812) 335-3575 x104280
Fax: (812) 332-0281
Date Prepared: June 28, 2016

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 predicate Roadrunner™ RLTF Wire Guide (K920824) is available in a 180 cm length and outer diameters of 0.014, 0.016, and 0.018 inches and utilizes identical materials as compared to the subject device. The flexible tip portion of the predicate device is formed into an angled configuration. The predicate device is intended for use in directing a percutaneous catheter into the cardiovascular system.

Comparison to Predicate Device:

The Roadrunner® Extra Support Wire Guide is identical in intended use, fundamental technological characteristics, principle of operation, and materials to the predicate device, Roadrunner™ RLTF Wire Guide (K920824). The only difference is an additional length.

Device Description:

The Roadrunner® Extra Support Wire Guide is manufactured in an outer diameter of 0.014 inches and lengths of 180 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.

There are no prior submissions for the subject device.

Discussion of Risk Mitigation Activities:

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:

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

- Rotational Response (Torqueability) Testing – Characterization testing was performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).
- Surface Analysis Testing – Characterization testing was performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).
- 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.
- Catheter Compatibility Testing – Testing was performed in accordance with BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Flex Testing on Aged Devices – Flex testing was repeated 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.

Conclusion:

The results of the risk mitigation activities support a conclusion that the Roadrunner® Extra Support Wire Guide is substantially equivalent to the predicate device.