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

Re: K182985
Trade/Device Name: Roadrunner PC Wire Guide, Olcott Torque Device
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 24, 2019
Received: June 25, 2019

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/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,

for Lydia Glaw, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182985

Device Name
Roadrunner® PC Wire Guide

Indications for Use *(Describe)*
The Roadrunner® PC Wire Guide is used for catheter positioning and exchange in diagnostic and interventional procedures, exclusive of the coronary arteries.

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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COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

510(k) SUMMARY

Submitted By: Daniel J. Corbin, RAC
Cook Incorporated
750 Daniels Way
Bloomington, IN 47404
Phone: (812) 335-3575 x104018
Fax: (812) 332-0281
Date Prepared: July 22, 2019

Device: **K182985**

Trade Name: Roadrunner® PC Wire Guide
Common Name: Catheter Wire Guide
Classification Name: Wire, Guide, Catheter
DQX (21 CFR §870.1330)

Indications for Use:

The Roadrunner® PC Wire Guide is used for catheter positioning and exchange in diagnostic and interventional procedures, exclusive of the coronary arteries.

Predicate Device:

The predicate device, the Roadrunner Wire Guide, was cleared for commercial distribution under 510(k) number K920891, on December 21, 1992.

Comparison to Predicate Device:

It has been demonstrated that the subject device, Roadrunner® PC Wire Guide is identical to the predicate device (K920891) in terms of intended use, principles of operation, basic technological characteristics, and similar in materials of construction. Additional wire guide lengths and mandril taper lengths have been included for the subject device as compared to the predicate device. A detailed comparison table of the predicate device and the device subject to this submission can be found in the following table.

COOK INCORPORATED
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BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Comparison Table of Predicate Device and Subject Device

		PREDICATE DEVICE	SUBJECT DEVICE
		Roadrunner Wire Guide (K920891)	**Roadrunner® PC Wire Guide** (Subject of this Submission)
Device Manufacturer		Cook Inc.	Cook Inc.
Regulation Number		21 CFR §870.1330	21 CFR §870.1330
Product Code		DQX	DQX
Classification		II	II
Intended Use		The Roadrunner wire guide is used for catheter positioning and exchange in diagnostic and interventional procedures, exclusive of the coronary arteries.	The Roadrunner® PC Wire Guide is used for catheter positioning and exchange in diagnostic and interventional procedures, exclusive of the coronary arteries.
Device Diameter (in)		0.025, 0.028, 0.032, 0.035, 0.038	0.035 and 0.038
Materials of Construction	**Mandril**	Nitinol	Identical
	Coils	Platinum	Identical
	Connections	Solder	Identical
	Outer Jacket	Polyurethane	Identical
	Surface Coating	Hydrophilic	Identical
Tip Shape		Straight, Angled	Identical
Wire Guide Length (cm)		30 - 240	80, 145, 180, and 260
Mandril Taper Length (cm)		Not discussed in detail	9, 10.5, 11.5, 18.5
Sterilization		EtO	Identical

Reference Device:

The reference devices used for the subject of this submission, The Roadrunner® PC Wire Guide, are K171997 – Mandril Wire Guide (cleared on March 30, 2018) and K130766 – Roadrunner Uniglide Hydrophilic Wire Guide (cleared on July 17, 2013).

Device Description:

The Roadrunner® PC Wire Guides, subject of this submission, have been modified from the predicate device, Roadrunner Wire Guide (K920891), to include additional lengths ranging from 80, 145, 180, and 260 centimeters. The modifications to the Roadrunner® PC Wire Guides have been created to provide additional options for physicians in selecting the appropriate wire guide during diagnostic and interventional procedures. The Roadrunner® PC Wire Guides are packaged, sterile devices intended for single patient use. There are no prior submissions for the subject device.

The Roadrunner® PC Wire Guide is constructed with a nitinol mandril secured with a solder connection to platinum coils at the distal tip. The device has an outer polyurethane jacket that

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spans the entire device. The length of the device is coated with a hydrophilic coating except the proximal 6 centimeters of the device. The device is available with an angled or straight distal tip. The wire guide is available in a 0.035 inch or 0.038 inch diameter and lengths of 80, 145, 180, and 260 centimeters. The subject device will be provided sterile and intended for single patient use. An Olcott Torque Device and a Wire Guide Inserter are provided with each subject device configuration.

Test Data:

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

- Biocompatibility Testing
- Corrosion Testing
- Resistance to Damage by Flex Testing
- Surface Examination Testing
- Simulated Use Testing
- Fracture Testing after Simulated Use Testing
- Tensile Testing after Simulated Use Testing
- Rotational Response (Torqueability) Testing
- Torque Strength Testing
- Catheter Compatibility Testing
- Radio-detectability Testing
- Distal Tip Deflection Testing
- Dimensional Analysis Testing
- Lubricity Testing
- Particulate Testing

All pre-determined acceptance criteria were met.

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