510(k) Summary

FEB - 2 2011

Submitted By:

Karen Bradburn, RAC
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Cook Incorporated
750 Daniels Way, PO Box 489
Bloomington, IN 47402
812-339-2235
December 23, 2010

Device:

Trade Name:	Roadrunner UniGlide Hydrophilic Wire Guide
Classification Name:	Wire, Guide, Catheter 21 CFR §870.1330
Device Classification:	Class II
Product Code:	DQX
Classification Panel:	Cardiovascular Panel

Indications for Use:

The Roadrunner UniGlide Hydrophilic Wire Guide is indicated for use in facilitating delivery of percutaneous catheters into the peripheral vasculature.

Predicate Devices:

The Roadrunner UniGlide Hydrophilic Wire Guide is identical to the Approach Hydro ST Wire Guide (K091385) in terms of intended use and similar to the Roadrunner Wire Guide (K920891) in terms of materials of construction and technological characteristics.

Device Description:

The Roadrunner UniGlide Hydrophilic Wire Guide is constructed of a nitinol mandril with a jacket made of polyurethane with tungsten, and is hydrophilically coated. These wire guides are constructed with a shaft diameter of either 0.018 inch, 0.025 inch, 0.035 inch, or 0.038 inch. They are manufactured in 80 cm, 150 cm, and 180 cm lengths and have a tapered, flexible tip. The 0.025 inch, 0.035 inch, and 0.038 inch versions of the Roadrunner UniGlide Hydrophilic Wire Guide are available in both standard and stiff configurations, while the 0.018 inch Roadrunner UniGlide Hydrophilic Wire Guide is available in the standard configuration only. The standard configurations have a 14 cm long tapered, flexible distal tip portion, whereas the stiff configurations have a 20 cm long tapered, flexible distal tip portion. The tip is manufactured in both straight and angled configurations. A torque device is supplied with the Roadrunner UniGlide Hydrophilic Wire Guide. The torque device is intended for use in complex diagnostic and interventional procedures and is designed for torque control.

Substantial Equivalence:

The Roadrunner UniGlide Hydrophilic Wire Guide is similar to many devices in commercial distribution for facilitating delivery of percutaneous catheters into the peripheral vascular system. Specifically, the identical indications for use and principles of operation and similar materials of construction and technological characteristics of the wire guide compared to the Approach Hydro ST and Roadrunner Wire Guides support a determination of substantial equivalence.

Test Data:

The Roadrunner UniGlide Hydrophilic Wire Guide was subjected to the following tests to assure reliable design and performance under the specified testing parameters.

1. Tensile Test
2. Tip Stiffness
3. Fracture Test
4. Flexing Test
5. Torque Testing
6. Lubricity Test
7. Biocompatibility Testing
8. Bioburden Testing
9. Endotoxin Testing
10. EtO Residual Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a wire guide.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cook, Inc.
c/o Karen Bradburn
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Bloomington, IN 47402-0489

FEB - 2 2011

Re: K110009
Trade/Device Name: Roadrunner UniGlide Hydrophilic Wire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: December 23, 2010
Received: January 3, 2011

Dear Ms. Bradburn:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

COOK INCORPORATED
Roadrunner UniGlide Hydrophilic Wire Guide
Special 510(k) Premarket Notification

510(k) Number (if known): K110009

Device Name: Roadrunner UniGlide Hydrophilic Wire Guide

Indications for Use: For use in facilitating delivery of percutaneous catheters into the peripheral vasculature.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over–the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110009