DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 29, 2016

Cook Incorporated
Jessica Swafford
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47402

Re: K161801
Trade/Device Name: CrossCath Support Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: June 29, 2016
Received: June 30, 2016

Dear Ms. Swafford:

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,

Brian D. Pullin -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)*
K161801

Device Name
CrossCath® Support Catheter

Indications for Use *(Describe)*
The CrossCath Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.

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.

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510(k) SUMMARY

Submitted By: Jessica Swafford
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Phone: (812) 335-3575 x104260
Fax: (812) 332-0281
Date Prepared: June 29, 2016

Device:

Trade Name:	CrossCath® Support Catheter
Common Name:	CXC Support Catheter
Classification Name:	Catheter, Continuous Flush KRA (21 CFR §870.1210)

Indications for Use:

The CrossCath Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.

Predicate Device:

The device, subject of this submission, is substantially equivalent to the predicate device, the CrossCath Support Catheters cleared under 510(k) number K093052.

Comparison to Predicate Device:

It has been demonstrated that the CrossCath Support Catheters are comparable to the predicate device. The CrossCath Support Catheters are identical in terms of intended use, principles of operation, and basic technological characteristics to the predicate device. An additional catheter length has been included and the substantial equivalence of the modification is supported by testing. Flow rate information included in the labeling has been updated to reflect this modification.

Device Description:

CrossCath Support Catheters are single lumen intravascular catheters, designed to support a wire guide during access of vasculature, allow for exchange of wire guides, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

CrossCath Support Catheters are available in 12 different configurations. All models have three radiopaque markers spaced equally along the distal shaft to aid in estimating length within the vascular system. The distal radiopaque marker is positioned approximately 3 millimeters from the catheter tip. Each model has a smaller distal portion for passing through smaller vasculature and a larger proximal portion for additional support. The distal 40 to 60 centimeters of each configuration are hydrophilically coated.

Test Data:

The following tests were performed to demonstrate that the modification to the CrossCath Support Catheters met applicable design and performance requirements and support a determination of substantial equivalence.

- Flow Rate – Measure flow rates through the device at designated injection pressures using saline and contrast.

In conclusion, the test results provide reasonable assurance to support a determination that the subject device is substantially equivalent to the predicate device.