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

November 22, 2016

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

Re: K160884
Trade/Device Name: CXI Support Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: March 29, 2016
Received: March 31, 2016

Dear Mr. 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. 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 yours,

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)*
K160884

Device Name
CXI™ Support Catheter

Indications for Use *(Describe)*
The CXI™ 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.

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510(k) SUMMARY

Submitted By:

Daniel J. Corbin
Cook Incorporated
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Phone: (812) 335-3575 x104018
Fax: (812) 332-0281
Date Prepared: October 25, 2016

Device:

Trade Name:	CXI™ Support Catheter
Common Name:	Continuous Flush Catheter
Classification Name:	Catheter, Continuous Flush KRA (21 CFR §870.1210)

Indications for Use:

The CXI™ 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 CXI™ Support Catheter cleared under 510(k) number K072724.

Comparison to Predicate Device:

The CXI™ Support Catheter is substantially equivalent to the predicate device, the CXI™ Support Catheter (K072724), in the following characteristics: identical intended use, identical fundamental technological characteristics, identical method of operation, and identical materials of construction. The CXI™ Support Catheter (subject of this submission) is available in two French sizes (2.6 and 4.0 French) and in four lengths (65, 90, 135, and 150 centimeters), whereas as the predicate CXI™ Support Catheter (K072724) was cleared with 2.6 French and 90 and 150 centimeter lengths. The CXI™ Support Catheter may be used coaxially with other CXI™ Support Catheters, i.e. the 2.6 French CXI™ Support Catheter may fit into and be used coaxially with the 4.0 French CXI™ Support Catheter. The substantial equivalence of the

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modified device to the predicate device is supported by testing summarized in this submission. Reference devices for this submission of the CXI™ Support Catheter (K160884) include the CXI™ Support Catheter (K122796) and CXI™ TriForce Peripheral Crossing Set (K111263).

Device Description:

The CXI™ Support Catheter with hydrophilic coating is a braided, kink-resistant catheter designed to facilitate wire guide exchange, wire guide support and to provide a conduit for the delivery of saline solutions or diagnostic contrast agents. The CXI™ Support Catheter will be available in catheter sizes of 2.6 and 4.0 French and with catheter lengths of 65, 90, 135, and 150 centimeters. The catheters will be supplied sterile and are intended for one-time use.

Test Data:

The following tests were performed to demonstrate that the CXI™ Support Catheter met applicable design and performance requirements and support a determination of substantial equivalence.

- Animal Testing – The testing showed that the devices were adequate or better in terms of the following performance parameters: preparation, introduction, pushability, trackability, flexibility, torquability, withdrawal, and inspection after use.

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