March 9, 2018

Cook Incorporated
Ms. Jennifer Allman, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K171764
Trade/Device Name: Fixed Core Wire Guides
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 7, 2018
Received: February 7, 2018

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)*
K171764

Device Name
Fixed Core Wire Guides

Indications for Use *(Describe)*
Fixed Core Wire Guides are intended to facilitate placement of devices used during diagnostic and interventional procedures.

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

Fixed Core Wire Guides
K171764
21 CFR §807.92
Date Prepared: March 8, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact:	Jennifer L. Allman
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x104280
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	**Fixed Core Wire Guides**
Common Name:	Wire, Guide, Catheter
Classification Name:	Catheter guide wire
Regulation:	21 CFR §870.1330
Product Code:	DQX

Predicate Device:

The InQwire® Merit Medical Guide Wire (Merit Medical Inc., K133230) is a fixed core wire guide intended to facilitate placement of devices during diagnostic and interventional procedures.

Reference Devices:

The following devices were referenced in the substantial equivalence discussion for the subject device:

Mandrel Guidewires or M-Wires (Lake Region Medical, K140485) cleared for market on September 24, 2014.

Sunmed Guide Wires (Sunny Medical Device (Shenzhen Co., Ltd., K120119) cleared for market on May 11, 2012.

ASAHI SION Blue PTCA Guide Wire (Asahi Intecc Co., Ltd., K122468) cleared for market on March 8, 2013.

Predicate III Guidewire (Lake Region Medical, K142393) cleared for market on November 25, 2014.

Device Description:
The Fixed Core Wire Guides, subject of this submission, are Class II devices according to 21 CFR §870.1330; product code DQX (Wire, Guide, Catheter). The subject device consists of a core mandril, a spring coil anchored over the mandril, and an inner safety wire. The Fixed Core Wire Guides are available with outside diameters ranging from 0.015 inches to 0.052 inches and lengths ranging from 15 centimeters to 480 centimeters. The flexible tip portion of the wire guides is either straight or J-tipped. The Fixed Core Wire Guides will be uncoated or coated with Polytetrafluoro-ethylene (PTFE). The Fixed Core Wire Guides are packaged, sterile devices intended for single use.

Intended Use:
The Fixed Core Wire Guides are intended to facilitate placement of devices during diagnostic and interventional procedures.

Comparison to Predicates:
The proposed Fixed Core Wire Guides and the predicate device, the InQwire Merit Medical Guide Wire (K133230), are substantially equivalent in that these devices have identical indications for use. The proposed Fixed Core Wire Guides are similar in design, technological characteristics, and materials to the InQwire Merit Medical Guide Wire (K133230).

Technological Characteristics:
The following tests were performed to demonstrate that the Fixed Core Wire Guides met applicable design and performance requirements and their results support a determination of substantial equivalence.

- Biocompatibility Testing – Tested in accordance with ISO 10993-1:2009. The pre-determined acceptance criteria were met.

- Corrosion Testing – Tested in accordance with Annex B of ISO 11070:2014. The pre-determined acceptance criteria were met.
- Flexing Test – Tested in accordance with the Annex G of ISO 11070:2014. The pre-determined acceptance criteria were met.
- Fracture Testing – Tested in accordance with Annex F of ISO 11070:2014. The pre-determined acceptance criteria were met.
- Tensile Testing – Tested in accordance with ISO 11070:2014, Annex H. The pre-determined acceptance criteria were met.
- Tip Flexibility – Characterization testing performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).
- Torque Strength Testing – Characterization testing performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).
- Acute Performance Evaluation – The acute performance of the subject device was evaluated in an animal model in accordance with an approved study protocol. The pre-determined acceptance criteria were met.

Conclusion:

The results of these tests support a conclusion that the Fixed Core Wire Guides met the design input requirements based on the intended use and support the conclusion that these devices do not raise new issues of safety or effectiveness. The results of these tests support a determination of substantial equivalence to the predicate device, the InQwire Merit Medical Guide Wire (K133230).