March 19, 2018

Cook Incorporated
Ms. Jennifer Allman, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47402

Re: K171912
Trade/Device Name: Double Flexible Tip Wire Guides
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 20, 2018
Received: February 20, 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,

for Kenneth J. Cavanaugh -S

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)*
K171912

Device Name

Double Flexible Tipped Wire Guides

Indications for Use *(Describe)*

The Double Flexible Tipped Wire Guides are used to facilitate the placement of devices 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

510(k) Number: K171912

Submitted By:

Jennifer L. Allman
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (812) 335-3575 x104280
Fax: (812) 332-0281
Date Prepared: March 19, 2018

Traditional 510(k) Premarket Notification

Device:

Trade Name:	Double Flexible Tipped Wire Guides
Common Name:	Catheter Wire Guide
Classification Name:	Wire, Guide, Catheter DQX (21 CFR §870.1330)

Indications for Use:

The Double Flexible Tipped Wire Guides are used to facilitate the placement of devices during diagnostic and interventional procedures.

Predicate Device:

The predicate device manufactured by Cook Incorporated, the Heavy Double Flexible Tip Wire Guide, was cleared for commercial distribution under 510(k) number K150802, on May 28, 2015.

Comparison to Predicate Device:

It has been demonstrated that the Double Flexible Tipped Wire Guides are identical to the predicate device (K150802) in terms of intended use, principles of operation, basic technological characteristics, sterilization method, packaging, and shelf life. The subject device is similar in materials of construction to the predicate device. Additional wire guide lengths, diameters, curve radii, PTFE coating, and a connection point have been included for the subject device as compared to the predicate device. The substantial equivalence of the subject device modifications are supported by performance and biocompatibility testing.

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Reference Devices:

- K140485, Mandrel Guidewires or M-Wires
- K142393, Predicate III Guidewire
- K081337, Approach CTO Wire Guide

Device Description:

The Double Flexible Tipped Wire Guides are Class II devices according to 21 CFR §870.1330; product code DQX (Wire, Guide, Catheter). The Double Flexible Tipped Wire Guides are wire guides with a flexible distal and proximal end. Double Flexible Tipped Wire Guides are intended to facilitate placement of devices used during diagnostic and interventional procedures.

The Double Flexible Tipped Wire Guides, subject of this submission, have been modified from the predicate device, Heavy Double Flexible Tipped Wire Guide (K150802), to include additional lengths ranging from 30 to 260 centimeters, additional outside diameters ranging from 0.018 to 0.038 inches, and additional curve radii ranging from 0 to 3 millimeters.

The Double Flexible Tipped Wire Guides are manufactured using a stainless steel core wire, and stainless steel coils. Some configurations include an exterior coating on the coils.

The modifications to the Double Flexible Tipped Wire Guides have been created to provide additional options for physicians in selecting the appropriate wire guide during diagnostic and interventional procedures.

The Double Flexible Tipped Wire Guides are packaged, sterile devices intended for single use.

There are no prior submissions for the subject device.

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Test Data:

The following tests were performed to demonstrate that the Double Flexible Tipped Wire Guides met applicable design and performance requirements and support a determination of substantial equivalence:

- Fracture Testing – Testing was performed in accordance with Annex F of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Tensile Testing – Testing was performed in accordance with Annex H of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Flexing Test – Testing was performed in accordance with Annex G of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Evaluation of Coating Integrity – The device coating was evaluated in accordance with BS EN ISO 11070:2014, Section 8.5, and Sub-section d. The device was evaluated for flaking of the coating using magnification to 40X.
- Torque Strength Testing – Characterization testing was performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).
- Tip Flexibility (Tip Deflection) Testing – Characterization testing was performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).
- Corrosion Testing – Testing demonstrated, when tested in accordance with Annex B of BS EN ISO 11070:2014, the device revealed no signs of corrosion that would affect functional performance. The pre-determined acceptance criteria were met.
- Catheter Compatibility Testing – Testing was performed in accordance with BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Biocompatibility Testing – Testing was performed in accordance with BS EN ISO 10993-1:2009, the materials and methods used to manufacture the subject device are non-toxic and met the pre-determined acceptance criteria for their intended use.

- Performance Testing on Aged Devices – Performance testing was repeated on aged devices in accordance with BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Acute Performance Evaluation – Evaluation of device performance in an animal model under conditions intended to simulate clinical use. All test articles evaluated met the predetermined acceptance criteria for all of the performance parameters.

Conclusion

In conclusion, the results of these tests support a determination that the Double Flexible Tipped Wire Guides met the design input requirements based on the intended use and support the conclusion that the modifications to the device 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 Heavy Double Flexible Tip Wire Guide (K150802).