June 14, 2018

Cook Incorporated
Ms. Jennifer Allman
Senior Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47402

Re: K181351
Trade/Device Name: Double Flexible Tipped Wire Guides
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 21, 2018
Received: May 22, 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 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,

Michael John -S
2018.06.14 14:46:55 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181351

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.

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510(k) SUMMARY

Submitted By: Jennifer L. Allman
Cook Incorporated
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Phone: (812) 335-3575 x104280
Fax: (812) 332-0281
Date Prepared: May 30, 2018

Submission: Special 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, is the Double Flexible Tipped Wire Guides, cleared for commercial distribution under 510(k) number K171912, on March 19, 2018.

Reference Device:
The reference device, manufactured by Cook Incorporated, is the Fixed Core Wire Guides cleared for commercial distribution under 510(k) number K171764 cleared for market on March 9, 2018.

Comparison to Predicate Device:
It has been demonstrated that the Double Flexible Tipped Wire Guides are identical to the predicate device (K171912) in terms of intended use, principles of operation, basic technological characteristics, and materials of construction. The subject device packaging, sterilization method, and shelf life have not changed from the predicate device. An additional wire guide diameter has been included for the uncoated subject device configuration as compared to the predicate device and coating has been added to existing predicate device configurations. The substantial equivalence of the subject device modification is supported by performance testing.

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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 have flexible distal and proximal ends. Double Flexible Tipped Wire Guides are used to facilitate the placement of devices during diagnostic and interventional procedures.

The Double Flexible Tipped Wire Guides, subject of this submission, have been modified from the predicate device, Double Flexible Tipped Wire Guides (K171912), to include an additional diameter of 0.015 inches to the uncoated configurations with lengths of 30, 40, and 60 centimeters. Additionally, the subject device has been modified from the predicate device to include coated configurations for the existing 0.021 and 0.025 inch diameter devices with lengths of 40, 50, and 60 centimeters.

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

The modification 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 patient use and labeled with a five-year shelf life.

There are no prior submissions for the subject device.

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:

- 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.
- Flexing Test – Testing was performed in accordance with Annex G of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Torque Strength Testing – Characterization testing was performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).

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- 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.
- Tip Flexibility (Tip Deflection) Testing – Characterization testing was performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).
- Catheter Compatibility Testing – Testing was performed in accordance with BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- 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.

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 questions of safety or effectiveness. The results of these tests support a determination of substantial equivalence to the predicate device, the Double Flexible Tipped Wire Guides (K171912).