



Food and Drug Administration
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May 28, 2015

Cook, Inc.
Ms. Julia Ferguson
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K150802

Trade/Device Name: Heavy Double Flexible Tipped Wire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 25, 2015
Received: March 26, 2015

Dear Ms. Ferguson:

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,

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

Indications for Use

510(k) Number (if known)

K150802

Device Name

Heavy Double Flexible Tipped Wire Guide

Indications for Use (Describe)

The Heavy Double Flexible Tipped Wire Guide is 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.

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COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Heavy Double Flexible Tipped Wire Guide
21 CFR §870.1310
Date Prepared: May 26, 2015

Submitted By:

Applicant: Cook Incorporated
Contact: Julia Ferguson
Applicant Address: Cook Incorporated
750 Daniels Way
Bloomington, IN 47404
Contact Phone Number: (812) 335-3575 x104554
Contact Fax Number: (812) 332-0281

Device Information:

Trade Name: Heavy Double Flexible Tipped Wire Guide
Common Name: Catheter Wire Guide
Classification Name: Wire, Guide, Catheter
Regulation: 21 CFR §870.1330
Product Code: DQX

Predicate Device:

The predicate device is the Cardiovascular Spring Guides (Lake Region Mfg., Inc., K770977).

Device Description:

The Heavy Double Flexible Tipped Wire Guide is constructed of stainless steel coils surrounding a stainless steel mandril. It is a 0.032 inch diameter, 60 cm long wire guide with two flexible tips and four sets of centimeter markings etched at 10 cm intervals along the wire shaft. The device is supplied sterile, packaged within a Tyvek peel pouch.

Intended Use:

The Heavy Double Flexible Tipped Wire Guide is intended to facilitate placement of devices used during diagnostic and interventional procedures.

Comparison to Predicates:

Cook Incorporated's Heavy Double Flexible Tipped Wire Guide is substantially equivalent to the predicate device, the Cardiovascular Spring Guides (K770977), in that these devices have identical designs, methods of construction and operation, and indications for use.

Technological Characteristics:

The following tests have been conducted to ensure reliable design and performance under the specified design requirements.

- **Fracture Testing:** Testing verified that there will be no signs of fracture after manipulation, excluding the region of fixation and the first turn. The predetermined acceptance criterion was met.
- **Tensile Testing:** Testing verified that there will be no sign of loosening of any unions after an appropriate level of force defined by ISO 11070:1999 is applied. The predetermined acceptance criterion was met.
- **Corrosion Resistance:** Testing verified that there will be no signs of corrosion that will affect the functional performance or biocompatibility of the wire guide. The predetermined acceptance criterion was met.
- **Flex Testing:** Testing verified that there will be no signs of defects or damage when the wire guide is subjected to repeated flexing. The predetermined acceptance criterion was met.
- **Acute Performance Evaluation:** The testing confirmed that the wire guide is rated as acceptable for normal clinical practice for the performance parameters evaluated. The predetermined acceptance criterion was met.
- **Bubble Leak (Packaging):** The package shall show no signs of pin holes or imperfect seals indicated by bubbles created from the pressurized air leaking into the surrounding solution. The predetermined acceptance criterion was met.
- **Seal Strength (Packaging):** All specimens must have a mean seal force that exceeds 0.50 lbf. The predetermined acceptance criterion was met.
- **Biocompatibility Testing:** Per ISO 10993-1:2009, the subject devices are categorized as external communicating devices in contact with circulating blood for a limited (≤ 24 hours) duration. The following tests were completed and the biocompatibility was deemed acceptable: cytotoxicity, sensitization, irritation/intracutaneous reactivity, systemic toxicity, and hemocompatibility.

Conclusion:

The results of these tests support a conclusion that the Cook Incorporated Heavy Double Flexible Tipped Wire Guide met the design input requirements based on its intended use. The results also support the conclusion that these devices do not raise new questions of safety or effectiveness and are substantially equivalent to the predicate device, the Cardiovascular Spring Guides (K770977).