Dear Jennifer 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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
2018.12.20 14:57:13 -05'00'
for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Disposable Reuter Tip Deflecting Wire Guides are intended for use in curving or deflecting catheter tips for pulmonary angiography, selective angiography, translumbar aortography, bronchography, repositioning of central venous catheter tips and other vascular and non-vascular applications.

Reuter Tip Deflecting Wire Guides are intended for use with the Reuter Tip Deflecting Handle assembly for curving or deflecting catheter tips for pulmonary angiography, selective angiography, translumbar aortography, bronchography, repositioning of central venous catheter tips and other vascular and non-vascular applications.

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

Reuter Tip Deflecting Wire Guide
21 CFR §807.92
Date Prepared: March 30, 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: Reuter Tip Deflecting Wire Guides
Common Name: Wire, Guide, Catheter
Classification Name: Catheter guide wire
Regulation: 21 CFR §870.1330
Product Code: DQX
Device Classification/Panel: Class II, Cardiovascular

Primary Predicate Device:
The predicate device is the Reuter Tip Deflecting Wire Guide (Cook Inc., D012681) granted pre-amendment status on April 28, 2014.

Reference Devices:
K171764, Fixed Core Wire Guides
K140485, Mandrel Guidewires or M-Wires
Device Description:
The Reuter Tip Deflecting Wire Guides, subject of this submission, are Class II devices according to 21 CFR §870.1330; product code DQX (Wire, Guide, Catheter). The subject devices are available with outer diameters of 0.025 and 0.035 inches, lengths of 80 – 145 centimeters, and a curved tip.

The subject device includes two configurations indicated by prefixes TDW and DTDW. Both configurations are constructed with stainless steel mandrils, coils, and internal handles. The coils cover the entire mandril and are secured using distal and proximal anchor points. The internal handle is permanently affixed to the proximal end of the wire guide and is designed to mate with the tip deflecting handle. The internal handle of the wire guide is not patient contacting.

The Reuter Tip Deflecting Wire Guide configuration with the TDW prefix is a disposable wire guide designed to be used with the Reusable Reuter Tip Deflecting Wire Guide handle which is not subject of this submission.

The Disposable Reuter Tip Deflecting Wire Guide configuration with the DTDW prefix is designed with a deflecting handle permanently affixed to the proximal end of the wire guide. The deflecting handle is manufactured from polycarbonate and stainless steel materials.

The purpose of the handle is to operate in a retracting motion thereby causing the tip of the connected wire guide to deflect to the specified radius.

The side-arm flushing adapter (Class II 510(k) exempt under product code DTL) is supplied with the Disposable Reuter Tip Deflecting Wire Guides as an accessory. The flushing adapter may be used to flush a catheter being used with the subject device during diagnostic and interventional procedures.

The subject device is a packaged, sterile device intended for single patient use.

Indication for Use:
Disposable Reuter Tip Deflecting Wire Guides are intended for use in curving or deflecting catheter tips for pulmonary angiography, selective angiography, translumbar aortography, bronchography, repositioning of central venous catheter tips and other vascular and non-vascular applications.

Reuter Tip Deflecting Wire Guides are intended for use with the Reuter Tip Deflecting Handle assembly for curving or deflecting catheter tips for pulmonary angiography,
selective angiography, translumbar aortography, bronchography, repositioning of central venous catheter tips and other vascular and non-vascular applications.

**Comparison to Predicates:**
The Reuter Tip Deflecting Wire Guide, subject of this submission, has been modified from the predicate Reuter Tip Deflecting Wire Guide (D012681), with the reuseable handle to include wire guide lengths of 110 and 145 centimeters, an additional diameter of 0.025 inches, a disposable handle configuration, and specific curve configurations of 5 and 10 millimeters.

**Technological Characteristics:**
The following tests were performed to demonstrate that the Reuter Tip Deflecting Wire Guide met applicable design and performance requirements and support a determination of substantial equivalence.

- Biocompatibility Testing – Tested in accordance with ISO 10993-1:2009. The predetermined acceptance criteria were met.
- Corrosion Testing – Tested in accordance with Annex B of ISO 11070:2014. The predetermined acceptance criteria were met.
- Flexing Test – Tested in accordance with the Annex G of ISO 11070:2014. The predetermined acceptance criteria were met.
- Surface Examination – Testing in accordance with Section 8.5 and Annex G of ISO 11070:2014, and an approved study protocol. The predetermined acceptance criteria were met.
- Fracture Testing – Tested in accordance with Annex F of ISO 11070:2014. The predetermined acceptance criteria were met.
- Tensile Testing of the Union of the Core Wire and Coil of the Guide Wire – Tested in accordance with the applicable values of ISO 11070:2014, Annex H. The predetermined acceptance criteria were met.
- Tensile Testing of the Union between the Deflecting Handle and the Wire Guide – Tested in accordance with the applicable values of ISO 11070:2017, Annex H.
- Dimensional and Catheter Compatibility Testing – Testing in accordance with an approved study protocol. The predetermined acceptance criteria were met.
- Radiopacity Testing – Testing in accordance with ASTM F640-12. The predetermined acceptance criteria were met.
Conclusion:
The results of these tests support a conclusion that the Reuter Tip Deflecting Wire Guides met the design input requirements based on the intended use and support the conclusion that the modifications 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 Reuter Tip Deflecting Wire Guide (D012681).