January 10, 2018

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

Re: K171445

Trade/Device Name: Amplatz Support Wire Guide with Apex Curve
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 7, 2017
Received: December 8, 2017

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,

Nicole G. Ibrahim -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

Device Name
Amplatz Support Wire Guide with Apex Curve

Indications for Use (Describe)

The Amplatz Support Wire Guide with Apex Curve is used to facilitate the placement of devices during diagnostic and interventional procedures. The Amplatz Support Wire Guide with Apex Curve is intended to facilitate the introduction and placement of interventional devices within the chambers of the heart including those used within trans-catheter aortic valve procedures.

Type of Use (Select one or both, as applicable)

- [x] 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

Amplatz Support Wire Guide with Apex Curve
21 CFR §807.92
Date Prepared: December 7, 2017

Submitted By:
Applicant: Cook Incorporated
Contact: Jennifer L. Allman
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: Amplatz Support Wire Guide with Apex Curve
Common Name: Wire, Guide, Catheter
Classification Name: Catheter guide wire
Regulation: 21 CFR §870.1330
Product Code: DQX

Predicate Devices:
The predicate device is the S-Wire Guidewire System cleared for market under K153397, on August 18, 2016.

Device Description:
The Amplatz Support Wire Guide with Apex Curve, subject of this submission, is a Class II device according to 21 CFR §870.1330; product code DQX (Wire, Guide, Catheter). The subject device utilizes a fixed core design. The Amplatz Support Wire Guide with Apex Curve is available with an outside diameter of 0.035 inches, a length of 260
centimeters, a curved tip, and an exterior coating. The Amplatz Support Wire Guide with Apex Curve is a packaged, sterile device intended for single patient use.

**Intended Use:**
The Amplatz Support Wire Guide with Apex Curve is used to facilitate the placement of devices during diagnostic and interventional procedures. The Amplatz Support Wire Guide with Apex Curve is intended to facilitate the introduction and placement of interventional devices within the chambers of the heart including those used within transcatheter aortic valve procedures.

**Comparison to Predicate:**
The Amplatz Support Wire Guide with Apex Curve, subject of this submission, and the predicate device, the S-Wire Guidewire System, are substantially equivalent in that these devices have identical indications for use. The subject device and the predicate device are both available in a 0.035 inch diameter, a 260 centimeter length, and a curved distal tip. The subject device is manufactured with a PTFE coating and the predicate device is manufactured with a PTFE coating on the shaft and silicone coating on the distal coil. The subject device is similar in design, technological characteristics, and materials to the S-Wire Guidewire System (K153397).

**Technological Characteristics:**
The following tests were performed to demonstrate that the Amplatz Support Wire Guide with Apex Curve 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.
- Fracture Testing – Tested in accordance with Annex F of ISO 11070:2014. The predetermined acceptance criteria were met.
- Radiopacity Testing – Testing in accordance with ASTM F640-12. The predetermined acceptance criteria were met.
- Tip Flexibility Testing – Testing in accordance with FDA Coronary and Cerebrovascular Guidewire Guidance. Testing was performed for characterization purposes.
- 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.
- Performance Testing of Aged Devices – Testing in accordance with ISO 11070:2014, Section 4.3 and Annex G. The predetermined acceptance criteria were met.
- Acute Performance Evaluation – Evaluation of device performance in an animal model under conditions intended to simulate clinical use. All of the test articles evaluated met the predetermined acceptance criteria for all of the performance parameters.

**Conclusion:**

The results of these tests support a conclusion that the Amplatz Support Wire Guide with Apex Curve met the design input requirements based on the intended use and support the conclusion this device does not raise new issues of safety or effectiveness. The results of these tests support a determination of substantial equivalence to the predicate device, the S-Wire Guidewire System (K153397).