DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 21, 2017

Cook Incorporated
Ms. Jennifer Allman
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K171897
Trade/Device Name: Approach CTO Microwire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, PDU
Dated: June 23, 2017
Received: June 26, 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.

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,

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

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)*
K171897

Device Name
Approach CTO Microwire Guide

Indications for Use *(Describe)*
The Approach CTO Microwire Guide is intended for use in facilitating delivery of percutaneous catheters into the peripheral vasculature and is also indicated for the intraluminal placement of percutaneous catheters or other therapeutic devices beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

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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5.0 510(k) SUMMARY

Approach® CTO Microwire Guide
21 CFR §807.92
Date Prepared: August 17, 2017

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:	**Approach® CTO Microwire Guide**
Common Name:	Wire, Guide, Catheter
Classification Name:	Catheter guide wire
Regulation/Product Code:	21 CFR §870.1330/DQX, PDU
Device Class/Panel:	Class II/Cardiovascular

Predicate Device:

The CiTop™ 0.014" Guidewire (Ovalum Ltd., K070212) is intended to facilitate the intra-luminal placement of the wire guide beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

Reference Device:

The Approach® CTO Microwire Guide, manufactured by Cook Inc., was cleared for commercial distribution under K081337 on August 8, 2008. The Approach® CTO Microwire Guide is intended for use in facilitating delivery of percutaneous catheters into the peripheral vasculature.

Device Description:

The Approach® CTO Microwire Guide, subject of this submission, is a Class II device according to 21 CFR §870.1330; product code DQX (Wire, Guide, Catheter). The subject device consists of a core mandril and a distal spring coil. The Approach® CTO Microwire Guide is available with an outside diameter of 0.014 inches and lengths ranging from 135 – 300 centimeters. The flexible tip portion of the wire guide is straight with tip loads ranging from 6 – 25 grams.

The Approach® CTO Microwire Guide is supplied with an insertion cannula which facilitates the insertion of the wire guide through valve assemblies.

The Approach® CTO Microwire Guide is a packaged, sterile device intended for single patient use.

Intended Use:

The Approach® CTO Microwire Guide is intended for use in facilitating delivery of percutaneous catheters into the peripheral vasculature and is also indicated for the intra-luminal placement of percutaneous catheters or other therapeutic devices beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

Comparison to Predicate:

The subject device is identical in indicated therapeutic effect to the predicate device, CiTop™ 0.014" Guidewire (K070212), which is intended to facilitate the intra-luminal placement of the wire guide beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

Comparison to Reference Device:

The subject device Approach® CTO Microwire Guide is identical in design, method of operation, fundamental technological characteristics, materials, manufacturing processes, and intended use to the reference device, the Approach® CTO Microwire Guide (K081337).

Performance Data:

The following tests were performed to demonstrate that the Approach® CTO Microwire Guide met applicable design and performance requirements and support a determination of substantial equivalence.

- Acute Performance Evaluation of the Cook Approach® CTO Microwire Guide in an Animal Model – This testing evaluated the preparation, introduction, push ability, track ability, flexibility, radiopacity, withdrawal, reintroduction, and interaction with supporting devices of the test articles under conditions intended to simulate clinical use. All (100%) of the test articles evaluated met the predetermined acceptance criteria for all of the performance parameters. No perforations or dissections were observed in this study.
- Acute Performance Evaluation of the Cook Approach® CTO Microwire Guide in a Cadaver Model – This testing evaluated the preparation, introduction, push ability, track ability, radiopacity, and interaction with supporting devices of the test articles under conditions intended to simulate clinical use. All test articles evaluated met the predetermined acceptance criteria for all of the performance parameters. Individual test article crossing success for this evaluation was 82% with a clinical success rate of 100%.

Summary of Literature Review

The following references demonstrate the use of the subject device, Approach® CTO Microwire Guide, in facilitating delivery of percutaneous catheters into the peripheral vasculature and for the intra-luminal placement of percutaneous catheters or other therapeutic devices beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention as well as supporting a determination of substantial equivalence to the predicate device:

- Mustapha, J.A., MD (2014). Lower Extremity CTO Crossing with the Saber™ Catheter. *Supplement to Endovascular Today*, *October* issue, pp. 19- pp. 22.

  This supplement includes a case report in which the subject device was used to cross a CTO cap in antegrade fashion.

- Rundback, John H., MD, FAHA, FSVM, Herman, Keven C., MD (2013). *Transpedal Interventions for Critical Limb Ischemia* [Vascular Disease Management 2013:10(8):E152-E158]. Retrieved from www.vasculardiseasemanagement.com

  This reference discusses favorable experiences with tools recommended in the setting of chronic total occlusion, one of which is the Approach CTO Microwire Guide.

- Scheinowitz, M. et al. (2009). Crossing Chronic Total Occlusions with a New 0.014" CiTop Guidewire: Proof of Concept. *Catheterization and Cardiovascular Interventions 74* (278–285). DOI 10.1002/ccd.

  This reference demonstrates equivalent crossing success of the predicate device as compared to the success demonstrated by the subject device in the performance evaluation determined in the cadaver model, discussed above.

Conclusion:

The results of the performance evaluation in animal and human models along with the literature review support a conclusion that the Approach® CTO Microwire Guide, subject of this submission, met the acceptance criteria based on the intended use and support the conclusion that the intended use for the subject device does not raise new questions of safety or effectiveness as compared to the predicate device, the CiTop™ 0.014" Guidewire (K070212).