510(k) Summary

Submitted By:

K081337

Karen Bradburn, RAC
Senior Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, PO Box 489
Bloomington, IN 47402
812-339-2235

AUG - 8 2008

Device:

Trade Name:	Approach CTO Wire Guide
Proposed Classification:	Wire, Guide, Catheter 21 CFR §870.1330

Indications for Use:

The Approach CTO Wire Guide is indicated for use in facilitating delivery of percutaneous catheters into the cardiovascular system.

Predicate Devices:

The Approach CTO Wire Guide is similar in terms of intended use, materials of construction and technological characteristics to predicate devices reviewed as devices for facilitating delivery of percutaneous catheters into the cardiovascular system.

Device Description:

The Approach CTO Wire Guide is manufactured using a stainless steel wire with a PTFE coating and a stainless steel and platinum distal tip. The maximum outside diameter is 0.0142-inch and will be available in 135, 190 and 300 cm lengths. It will be supplied sterile, intended for one-time use.

Substantial Equivalence:

The Approach CTO Wire Guide is similar to many devices in commercial distribution for facilitating delivery of percutaneous catheters into the cardiovascular system. The identical indications for use, principles of operations, similar materials of construction and technological characteristics of the wire guide support a determination of substantial equivalency.

Test Data:

The Approach CTO Wire Guide was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Tensile Test
2. Tip Load Test
3. Fracture Test
4. Flexing Test
5. Bending Test
6. Torque Strength Test
7. Torque Response Test
8. Corrosion Resistance Test
9. Biocompatibility Testing
10. Bioburden Testing
11. Endotoxin Testing
12. EtO Residual Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a wire guide.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen Bradburn, RAC
Senior Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

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Re: K081337
Trade/Device Name: Approach CTO Wire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II
Dated: July 10, 2008
Received: July 11, 2008

Dear Ms. Bradburn:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-3150. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K081337

Device Name: Approach CTO Wire Guide

Indications for Use:

Indicated for use in facilitating delivery of percutaneous catheters into the cardiovascular system.

Prescription Use __X___ (Per 21 CFR 801 Subpart D) OR Over–the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochman A

(Division Sign-Off)
Division of Cardiovascular Devices

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