COOK INCORPORATED
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JAN 29 2014

510(k) SUMMARY

Submitted By: Jennifer Richardson, MA
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (812) 335-3575 x102370
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Date Prepared: December 20, 2013

Device:

Trade Name:	Advance® CS Coronary Sinus Infusion Catheter
Common Name:	Percutaneous Catheter
Classification:	Class II, Product Code: DQY, (21 CFR §870.1250)

Indications for Use:
The Advance® CS Coronary Sinus Infusion Catheter is intended for temporary occlusion of the coronary sinus for infusion of contrast media, drugs, or therapeutic agents; or possible introduction of devices into the coronary venous system.

Device Description:
The Advance® CS Coronary Sinus Infusion Catheter is an over-the-wire catheter. The 5.0 Fr balloon catheter is compatible with a 0.035 inch diameter wire guide. The device will be supplied sterile and intended for one-time use.

Comparison to Predicate Device:
The proposed device is substantially equivalent to the predicate in terms of intended use, duration of use, principles of operation, and technological characteristics.

Discussion of Tests and Test Results:
The device was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Balloon Minimum Burst Strength – Testing shows the balloons will burst at or above the minimum rated burst pressure, with all failure modes being linear tears. The predetermined acceptance criteria were met.
2. Sheath Compatibility – Qualitative and quantitative evaluations show that the balloons are compatible with a 5, 6, or 7 Fr sheath. The predetermined acceptance criteria were met.
3. Balloon Profile – Measurement of the diameter of catheter shaft, bonds, and folded balloon shows that the device profile is compatible with a 5, 6, or 7 Fr sheath (0.074, 0.087, or 0.100 inch profile). The predetermined acceptance criteria were met.

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4. Balloon Compliance – Testing shows that the balloon will inflate to the stated balloon size. The predetermined acceptance criteria were met.
5. Dynamic Burst of the Distal Lumen – Testing characterized saline and contrast agent flow rate vs. pressure curves. Testing shows that all test articles withstood at least pressures in excess of 300 psig regardless of injection media type. The predetermined acceptance criteria were met.
6. Static Burst of the Distal Lumen – Testing shows that similar test articles can be expected to fail at or above 100 psig. The predetermined acceptance criteria were met.
7. Freedom from Leakage – Testing shows that the balloon catheter will withstand pressurization to 200 psi for a time period of 15 seconds without leaking or significantly increasing in outside diameter. The predetermined acceptance criteria were met.
8. Balloon Fatigue – Testing shows that balloons are free from leakage and damage on inflation, withstanding 10 cycles of inflation/deflation. The predetermined acceptance criteria were met.
9. Bond and Materials Strength – Testing shows the tensile force during normal use should not fracture or rupture the balloon catheter bonds or materials. The predetermined acceptance criteria were met.
10. Inflation / Deflation Time – Testing shows that the balloon will inflate within 60 seconds and fully deflate within 60 seconds. The predetermined acceptance criteria were met.
11. Torque Strength - Testing shows that the catheter will withstand two full rotations without failure.
12. Kink and Flexibility – The testing shows that the catheter will not kink at a radius equal to or greater than 13mm.
13. Particulate – The testing shows that the balloon will not create particulates that exceed that of the reference limits.
14. Dimensional Verification – The testing shows that the devices will meet dimensional specifications.
15. Animal Evaluation – *In vivo* testing characterized the safety and biologic response approximately 48 hours following the acute inflation of the balloon in the porcine coronary sinus.
16. Biocompatibility – Testing (i.e., cytotoxicity, sensitization, irritation, systemic toxicity, hemocompatibility) shows the device is biocompatible. In conformance with the applicable sections of ISO 10993-1, the predetermined acceptance criteria were met.

Conclusions Drawn from the Tests:
The results of these tests provide reasonable assurance that the device is as safe and effective as the predicate device and support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 29, 2014

Cook Incorporated
c/o Ms. Jennifer Richardson, MA
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

Re: K131204
Trade/Device Name: Advance® CS Coronary Sinus Infusion Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Advance® CS Coronary Sinus Infusion Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 30, 2013
Received: December 31, 2013

Dear Ms. Richardson:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

Cook Incorporated
Advance® CS Coronary Sinus Infusion Catheter
Traditional 510(k)
26 April 2013

Indications for Use Statement

510(k) Number (if known): K131204

Device Name: Advance CS Coronary Sinus Infusion Catheter

Indications for Use:

The Advance CS Coronary Sinus Infusion Catheter is intended for temporary occlusion of the coronary sinus for infusion of contrast media, drugs, or therapeutic agents; or possible introduction of devices into the coronary venous system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner