Special 510(k): Device Modification
Occlusion Balloon Catheter
Cook Incorporated
2 July 2010

510(k) SUMMARY

Submitted By: Lisa Webb, MBA, RAC
Cook Incorporated
750 Daniels Way
Bloomington, IN 47404

Device:

Trade Name: Occlusion Balloon Catheter
Proposed Classification: Catheter, Percutaneous
DQY (21 CFR §870.1250)

Indications for Use:

The Occlusion Balloon Catheter is intended for temporary occlusion of large vessels.

Predicate Device:

The Occlusion Balloon Catheter is similar in terms of intended use, method of operation, materials of construction, and technological characteristics to the predicate device which was cleared as the CODA Balloon Catheter (K032869).

Device Description:

The Occlusion Balloon Catheter is a triple lumen balloon catheter designed to temporarily occlude large vessels. The "Infusion" lumen is used to infuse contrast material through the catheter. The "Distal .035" lumen extends the length of the catheter and is used for placement over wire guides. The "Balloon" lumen is used to inflate and deflate the balloon.

The Occlusion Balloon Catheter is available in one configuration. The catheter has two radiopaque marker bands on the shaft, enclosed within the balloon bonds, to help identify the location of the balloon under fluoroscopy. The balloon has a variable diameter up to a maximum of 40 mm when inflated and a catheter length of 75 cm.

Substantial Equivalence:

Cook Incorporated currently markets the predicate CODA Balloon Catheter, which was cleared for market on November 19, 2003 (K032869). The similar indications for use, method of operation, and technological characteristics of the Occlusion Balloon Catheter as compared to the predicate device support a determination of substantial equivalence.

Test Data:

The proposed Occlusion Balloon Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters.

- Burst Pressure Testing
- Bond Strength Testing
- Tensile Testing
- Fatigue Testing
- Sheath Compatibility Testing
- Inflation/Deflation Time
- Occlusion Testing
- Accelerated Aged Testing
- Biocompatibility Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to ensure conformance to the requirements for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 06 2010

Cook, Inc.
c/o Ms. Lisa Webb
Regulatory Affairs Manager
750 Daniels Way
Bloomington, IN 47402

Re: K101877
Trade/Device Name: Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: July 2, 2010
Received: July 6, 2010

Dear Ms. Webb:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K101877

Device Name: Occlusion Balloon Catheter

Indications for Use for the Occlusion Balloon Catheter:

The Occlusion Balloon Catheter is intended for temporary occlusion of large vessels.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101877