K122917

510(k) Summary

Submitted By:

JUN 28 2013

Elysia Easton
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
812-339-2235

Device:

Trade Name:	Coda Balloon Catheter
Common/Usual Name:	Occlusion Balloon Catheter
Proposed Classification:	Catheter, Percutaneous (74 DQY)

Indications for Use:
Intended for temporary occlusion of large vessels, or to expand vascular prostheses.

Predicate Devices:
Coda Balloon Catheter cleared under the following 510(k) Premarket Notification:

- K032869, November 19, 2003

Device Description:
The Coda Balloon Catheter is a 10.0 French device measuring 120 or 140 cm in usable length. The Coda Balloon Catheter shaft contains two independent lumens. The distal lumen extends the length of the catheter and is used for placement over a 0.035 inch diameter wire guide. The balloon (inflation and deflation) lumen extends from the proximal hub to the inflation ports within the balloon. The maximum inflation diameter is 46 mm, with a corresponding maximum balloon inflation volume of 60 mL. The device will be supplied sterile, intended for one-time use.

Substantial Equivalence:
The identical indications for use and technological characteristics of the Coda Balloon Catheter as compared to the predicate device support a determination of substantial equivalence.

Comparison to Predicate Device:
The Coda Balloon Catheter has been modified from the predicate Coda Balloon Catheter to include a balloon diameter of 46 mm and an additional catheter length of 140 cm. It has been demonstrated that the Coda Balloon Catheter is comparable to the predicate device in terms of design, intended use, materials, fundamental technology, and principle of operation.

Test Data:
The Coda Balloon Catheter 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 and Compliance – Testing demonstrates the minimum rated burst volume of the test article, calculated for 99% coverage and 95% confidence, is greater than the 60 mL inflation volume corresponding to a 46 mm balloon diameter. The predetermined acceptance criteria were met.

2. Occlusion and Migration – Testing demonstrates, at the 95% confidence level and with 90% minimum coverage, the ability to occlude a mock vessel when pressurized without any evidence of liquid leakage or migration. The predetermined acceptance criteria were met.

3. Balloon Fatigue – Testing shows that balloons are free from leakage and damage on inflation, withstanding 40 cycles of inflation/deflation (20 unconstrained/20 constrained). The predetermined acceptance criteria were met.

4. Inflation/Deflation Time – Testing statistically demonstrates that 90% of the overall population from which test articles were sampled have an inflation and deflation time (independently evaluated) below 30 seconds with a 95% confidence level. The predetermined acceptance criteria were met.

5. Simulated Use – Simulated use testing in a vascular prosthesis and anatomical model shows both devices are compatible with the recommended sheath and wire guide and perform according to the instructions for use. The predetermined acceptance criteria were met.

6. Catheter Usable Length – Testing verifies usable catheter length to the specified length ± 2 cm. The predetermined acceptance criterion was met.

In conclusion, 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

June 28, 2013

Cook Incorporated
C/O Elysia Easton
Regulatory Affair Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K122917
Trade/Device Name: Coda® Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 30, 2013
Received: May 31, 2013

Dear Ms Easton:

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.

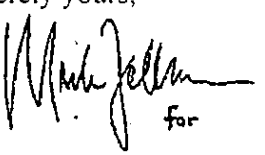
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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

Enclosure

Special 510(K) Premarket Notification
Coda Balloon Catheter
Cook Incorporated
September 21, 2012

510(k) Number (if known): K122917

Device Name: Coda Balloon Catheter

Indications for Use:

Intended for temporary occlusion of large vessels, or to expand vascular prostheses.

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)