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

May 12, 2015

Cook Incorporated
Chad Schulenburg
Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47404

Re: K150970
Trade/Device Name: Coda LP Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 10, 2015
Received: April 13, 2015

Dear Chad Schulenburg:

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 yours,

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)*
K150970

Device Name
Coda® LP Balloon Catheter

Indications for Use *(Describe)*
The Coda® LP Balloon Catheter is intended for the temporary occlusion of large vessels, or to expand vascular prostheses.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Submitted By:

Chad Schulenburg, MA
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Phone: (812) 335-3575 x104073
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Date Prepared: May 12, 2015

Device:

Trade Name:	Coda® LP Balloon Catheter
Common Name:	Occlusion Balloon Catheter
Classification Name:	Catheter, Percutaneous DQY (21 CFR §870.1250)

Indications for Use:

The Coda® Low Profile Balloon Catheter is intended for the temporary occlusion of large vessels, or to expand vascular prostheses.

Predicate Devices:

The device subject of this submission is substantially equivalent to the predicate devices, cleared for market under 510(k) numbers K032869 on November 19, 2003 and K122917 on June 28, 2013.

Comparison to Predicate Devices:

It has been demonstrated that the Coda LP Balloon Catheters are comparable to the predicate devices. The Coda LP Balloon Catheters are identical in terms of intended use, principles of operation, materials of construction, and basic technological characteristics to the predicate devices. The device changes consist of a balloon with a smaller diameter and volume, and a smaller catheter French size. The Coda LP Balloon Catheters are also used through a smaller introducer sheath. The safety and effectiveness of the modifications are supported by testing.

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Device Description:

The Coda LP Balloon Catheters are over-the-wire catheters that are available with an inflated balloon diameter of 32 millimeters and a balloon volume of 30 cc. The catheters are 9.0 French and are available in lengths of 100 or 120 centimeters. The Coda LP Balloon Catheter shaft contains two independent lumens within a single extrusion. 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 two inflation media exit ports within the balloon. The catheters are supplied sterile and are intended for one-time use.

Test Data:

The following tests were performed to demonstrate that the Coda LP Balloon Catheters met applicable design and performance requirements and support a determination of substantial equivalence.

- Balloon Burst Testing – Testing showed that the balloons burst above the maximum rated volume, with all failures being non-fragmentary. The acceptance criteria were met.
- Balloon Inflation/Deflation Testing – Testing showed that the balloons inflated to rated burst pressure within 30 seconds and fully deflated within 30 seconds. The acceptance criteria were met.
- Simulated Use Testing – Testing showed that the catheters were capable of being inserted into and retracted from an appropriately sized sheath without experiencing excessive resistance. Testing showed that this device was able to expand an endovascular graft by inflating the balloon. The acceptance criteria were met.
- Fatigue Testing – Testing showed that the balloons were free from leakage and damage on inflation, withstanding 40 cycles of inflation/deflation. The acceptance criterion was met.
- Occlusion and Migration Testing – Testing showed that this device was able to occlude fluid flow without migrating. The acceptance criteria were met.
- Tensile Strength Testing – Testing showed that under proper clinical use of the device, the peak load values were in accordance with the acceptance criteria.

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Conclusion:

In conclusion, the results of these tests support a determination of substantial equivalence to the predicate devices.