510(k) SUMMARY

DEC 14 2012

Submitted By: Amber Brown
Cook Incorporated
750 Daniels Way
Bloomington, IN 47404

Device:

Trade Name: Slip-Cath® Beacon® Tip Catheter and Shuttle® Select Slip-Cath® Catheter

Proposed Classification: Catheter, Diagnostic Intravascular
DQO (21 CFR §870.1200)

Indications for Use:

The Slip-Cath® Beacon® Tip Catheter and Shuttle® Select Slip-Cath® Catheter are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques.

Predicate and Reference Devices:

Cook Incorporated's Slip-Cath® Beacon® Tip Catheters and Shuttle® Select Slip-Cath® Catheters are similar in terms of intended use and similar in terms of principles of operation, materials of construction, and technological characteristics to the predicate and reference devices. The devices, subject of this submission, are substantially equivalent to the Slip-Coat™ Catheters, manufactured by Cook Incorporated, which are cleared under 510(k) number K882796 and the reference device, Cantata Microcatheter, which is cleared under 510(k) number K101450.

Comparison to Predicate and Reference Devices:

It has been demonstrated that the Slip-Cath® Beacon® Tip Catheter and Shuttle® Select Slip-Cath® Catheter are comparable to the predicate and reference devices in terms of design, intended use, materials, fundamental technology, and principles of operation.

Device Description:

The Slip-Cath® Beacon® Tip Catheters and Shuttle® Select Slip-Cath® Catheters are visually identified by a distal radiopaque tip bonded onto a stainless steel braided catheter shaft. Slip-Cath® Beacon® Tip Catheters and Shuttle® Select Slip-Cath® Catheters are manufactured in lengths of 40, 60, 65, 75, 80, 90, 100, 125, 135 and 150 centimeters and have no distal sideports. Each catheter is manufactured with either a plastic winged hub mounted on the proximal end of the catheter, indicating the catheter French size and relative endhole diameter, or a translucent hub with a strain relief. The catheters are

manufactured with a 4.0, 4.1, 4.5, 5.0, 5.5 or 6.5 French catheter shaft that is designed with an inner lumen tapered to a 0.035 or a 0.038 inch endhole diameter. These catheters are manufactured in a variety of distal tip configurations.

Test Data:

The following tests were performed to demonstrate that the Slip-Cath® Beacon® Tip Catheters and Shuttle® Select Slip-Cath® Catheters meet applicable design and performance requirements and support a determination of substantial equivalence. Additionally, appropriate engineering tests were performed on aged product to ensure that the Slip-Cath® Beacon® Tip Catheters and Shuttle® Select Slip-Cath® Catheters meet the performance requirements throughout the duration of shelf life.

- Tensile Strength – Testing shows the tensile strength during proper clinical use should not fracture or rupture the catheter. In conformance with the applicable sections of ISO 10555-1, the predetermined acceptance criteria were met.
- Leakage – Testing shows there would be no leakage from the catheter during proper clinical use. In conformance with the applicable sections of ISO 10555-1, the predetermined acceptance criteria were met.
- Biocompatibility – Testing shows the device is biocompatible. In conformance with the applicable sections of ISO 10993-1, the predetermined acceptance criteria were met.

In conclusion, the results of these tests provide reasonable assurance that the device is as safe and effective as the predicate and reference devices and supports 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 20993-002

Cook, Inc.
Ms. Amber Brown
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

DEC 14 2012

Re: K122937
Trade Name: Slip-Cath® Beacon® Tip Catheter and Shuttle® Select Slip-Cath® Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: November 14, 2012
Received: November 15, 2012

Dear Ms. Brown:

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): K122937

Device Name: Slip-Cath® Beacon® Tip Catheter and Shuttle® Select Slip-Cath® Catheter

Indications for Use for the Slip-Cath® Beacon® Tip Catheter and Shuttle® Select Slip-Cath® Catheter:

The catheters are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques.

Prescription Use XX (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 K122937