Special 510(k) Premarket Notification
Cantata™ Microcatheter
COOK INCORPORATED

K101450

510(k) Summary

DEC 30 2010

Submitted By:
Mironda Carpenter
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
812.339.2235

22 December 2010

Device:

Trade Name:	Cantata™ Microcatheter
Proposed Classification:	Catheter, Continuous Flush KRA

Indications for Use:

The Cantata™ Microcatheter is designed for use in small vessel or superselective anatomy for diagnostic and interventional procedures including neuro, peripheral, or coronary use.

Predicate Devices:

The Cantata™ Microcatheter is identical in terms of intended use and technological characteristics and similar in terms of material with the predicate MiraFlex®18 Microcatheter cleared under 510(k) number K060224 and the MiraFlex® High Flow Microcatheter cleared under 510(k) number K080737. The change involves a conversion from the current hydrophilic coating to a differently formulated hydrophilic coating.

Device Description:

The Cantata™ Microcatheter is an infusion catheter with a hydrophilic coating, designed for use in small vessel or superselective anatomy for diagnostic and interventional procedures. The device is available in 2.5 and 2.8 French shafts and is available in 100, 110, 135, and 150 cm lengths. The device is supplied sterile and intended for one-time use.

Substantial Equivalence:

The Cantata™ Microcatheter is substantially equivalent to the predicate MiraFlex®18 Microcatheter cleared under 510(k) number K060224 and MiraFlex® High Flow Microcatheter cleared under 510(k) number K080737.

Test Data:

The Cantata™ Microcatheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were:

1. Tensile strength
2. Static burst pressure
3. Kink radius
4. Coating durability and lubricity
5. Biocompatibility
    a. Cytotoxicity
    b. Sensitization, Maximization
    c. Intracutaneous
    d. Systemic Toxicity
    e. Hemolysis
    f. Pyrogen
    g. Complement Activation
    h. ASTM Partial Thromboplastin Time
6. Shelf life
7. Endotoxin/bioburden
8. Particulate Testing

A rationale based upon the geometry, conditions of use and the materials that interact with the blood was submitted to support the omission of the *in vivo* thrombogenicity testing.

The results of these tests provide reasonable assurance that the device has been designed and tested to assure 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

Cook Incorporated
c/o Ms. Mironda Carpenter
Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

DEC 30 2010

Re: K101450
Trade/Device Name: Cantata™ Microcatheter
Common Name: Catheter, Continuous Flush
Regulation Number: 21 CFR 870.1210
Regulatory Class: II
Product Code: KRA
Dated: December 17, 2010
Received: December 20, 2010

Dear Ms. Carpenter:

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,

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

Enclosure

Indications for Use

DEC 3 0 2010

510(k) Number (if known): K101450

Device Name: Cantata™ Microcatheter

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Prescription Use ___X___ (Per 21 CFR 801 Subpart D) OR Over-the-Counter Use _____ (Per 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101450