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K131772

FEB 20 2014

510(K) Summary

Cantata® 2.9 Microcatheter

Submitter Information:

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Contact:	Jennifer A. Richardson, MA
Email:	jennifer.richardson@cookmedical.com
Contact Phone Number:	(812) 339-2235 ext. 2370
Contact Fax Number:	(812) 332-0281

Date Prepared: December 24, 2013

Device Information:

Trade Name:	Cantata® 2.9 Microcatheter
Common Name:	Continuous Flush Catheter
Classification Name:	Catheter, Continuous Flush KRA (21 CFR §870.1210)

Purpose of Submission:
The purpose of this submission is to expand the offering of COOK Inc. Cantata® Microcatheters to include a 2.9 French, 0.027 inch (0.69 millimeters) inner diameter microcatheter. The 2.9 French Cantata® Microcatheter will complement the existing 2.5 French and 2.8 French Cantata® Microcatheters.

Indications for Use:

The Cantata® 2.9 Microcatheters are intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures including neuro, peripheral, or coronary use.

Predicate Device:

The Cantata® 2.9 Microcatheters are identical in terms of intended use, principles of operation, and technological characteristics to the predicate devices. The device, subject of this submission, is substantially equivalent to the Cantata® Microcatheters cleared under 510(k) number K101450.

Comparison to Predicate Device:

It has been demonstrated that the Cantata® 2.9 Microcatheters are comparable to the predicate device. The predicate devices and the device subject of this submission are intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures including neuro, peripheral, or coronary use. The predicate and proposed devices are completely identical in terms of overall design and indications for use.

Device Description:

The Cantata® 2.9 Microcatheters are braided microcatheters with hydrophilic coating, designed for use in small vessel or superselective anatomy for diagnostic and interventional procedures including neuro, peripheral, or coronary use. The devices include one radiopaque marker band to assist in fluoroscopic visualization of the catheter during use. The catheters are available in 2.9 French shafts and are available in 100, 110, 135, and 150 centimeter lengths. The devices are compatible with a 0.038 inch (0.97 millimeters) diameter angiographic catheter and can accept 0.018 inch (0.46 millimeters) and 0.021 inch (0.53 millimeters) diameter wire guides.

Test Data:

The following tests were performed to demonstrate that the Cantata® 2.9 Microcatheters met applicable design and performance requirements and supports a determination of substantial equivalence.

Table 1 Cantata® 2.9 Microcatheter Test Data

Test	Methodology	Conclusions
Air Leakage Testing	Test article is loaded with de-aerated processed water and subjected to a negative pressure after occluding the lumen. Visual inspection for air bubbles is subsequently conducted for fifteen seconds.	Testing showed that the catheter does not exhibit air leakage during proper clinical use. Device met the predetermined acceptance criteria.
Liquid Leakage Testing	Test article is loaded with processed water and subjected to a pressure of 300 kPa to 320 kPa after occluding the lumen. Visual inspection for air bubbles is subsequently conducted for a minimum of 30 seconds.	Testing shows that the catheter shall not leak liquid during proper clinical use. Testing demonstrated that the device met the predetermined acceptance criteria.

Table 1 Cantata® 2.9 Microcatheter Test Data (continued)

Tensile Testing	A uniaxial tensile load was applied to evaluate all four durometer transition zones of the test article shaft to ensure the resulting force required to break the shaft was greater than 5 Newtons.	Testing showed that under proper clinical use of the device the peak load value shall be greater than 5 Newtons. In conformance with ISO 10555-1:1995, the predetermined acceptance criteria were met.
Kink Radius Testing	The distal segment of the test article shaft was passed through a kink radius fixture to create a loop in the device. Both end of the device were then slowly pulled to close the loop until a kink was formed in the shaft. This process was recorded by an image analysis system which was used to determine the radius of the loop immediately prior to kinking.	Testing showed that under proper clinical use the kink radius of the device is ≤ 3 millimeters. Testing demonstrated that the device met the predetermined acceptance criteria.
Dynamic Failure Pressure Testing	Test articles are subjected to a dynamic flow of saline at 1000 psi +50 psi / 0 psi and examined for leaking, rupture, or swelling of the shaft greater than twice the original diameter.	Testing demonstrated that under proper clinical use the device can withstand a pressure of 1000 pounds per square inch without signs of failure. Testing demonstrated that the device met the predetermined acceptance criteria.
Injection Pressures and Flow Rate Testing	Test article are subjected to dynamic flow or various injection fluids at given pressure steps. The fluid through the lumen of the device during injection is measure and divided by the time that the pressure was applied to create a flow rate.	Injection pressures and flow rates of the device were characterized.

Table 1 Cantata® 2.9 Microcatheter Test Data (continued)

Embolic Particle Size Testing	Embolic particles are prepared and delivered through the device per their corresponding Instructions for Use. Failure is considered to have occurred if the lumen of the device is completely blocked during delivery and the entire batch of particles cannot be delivered.	The device can deliver embolic particles in the 710 – 1000 micron range.
Ancillary Device Compatibility Testing	The device was advanced over a standard microwire guide and through a 0.038" inner diameter angiographic catheter placed in a simulated tortuosity fixture to ensure device compatibility.	Device is compatible with a Standard micro wire guide and a 0.038 inch diameter angiographic catheter.
Evaluation of Device in an Animal Model	The device was qualitatively evaluated for performance criterion of preparation, introduction, pushability, trackability, and radiopacity in an animal model.	The device and the compatible device/embolization medium must receive an acceptable rating in terms of preparation, introduction, pushability, trackability, and radiopacity.
Trackability Testing	The device was inserted through an angiographic catheter and tracked over a micro wire guide through a model of the internal carotid artery. Testing was considered successful if the device was able to be successfully tracked to the internal carotid artery siphon.	Testing showed that the device is able to be consistently tracked to the location of the internal carotid artery siphon. Testing demonstrated that the device met the predetermined acceptance criteria.
Cytotoxicity – ISO MEM Elution Assay	When scoring lysis, the test article score a 0 (same as negative and cell control) at 24, 48, and 72 ± 4 hours.	Non-cytotoxic

Table 1 Cantata® 2.9 Microcatheter Test Data (continued)

Sensitization	None of the negative animals challenged with the control vehicle, or the animals challenged with the test article extracts were observed with a sensitization response great then '0'. The normal saline extract and cottonseed oil extract of the test material had a sensitization response of '0' under valid test conditions.	The test article did not elicit a sensitization response
Intracutaneous Reactivity	The differences in the mean test and control scores of the extract dermal observations were less and 1.0	The requirements of the ISO Intracutaneous Reactivity Test have been met
Systemic Toxicity	None of the test article treated animals were observed with clinical signs consistent with toxicity at any of the observations periods.	The requirements of the ISO Acute System Injection Test have been met
Hemolysis	Test article exhibited an Average Blank Corrected % Hemolytic Index of % (same as blank control)	Non-hemolytic
Complement Activation	Under conditions of the C3a assay the test article and the comparison article activation at 2.1% and 3.5%, respectively, of the normalized C3a concentration produced by CVF	No ranges or levels established as acceptable
Partial Thromboplastin Time	The test article had an average clotting time 297.0 seconds (99% of the negative control)	Minimal-activator of intrinsic coagulation pathway

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

February 20, 2014

Cook Inc.
Ms. Jennifer A. Richardson
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47402

Re: K131772
Trade/Device Name: Cantata® 2.9 Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II
Product Code: KRA, DQY
Dated: June 14, 2013
Received: December 24, 2013

Dear Ms. Richardson:

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,

Joyce M. Whang -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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 on last page.

510(k) Number *(if known)*
K131772

Device Name
Cantata® 2.9 Microcatheters

Indications for Use *(Describe)*
The Cantata® 2.9 Microcatheters are intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures including neuro, peripheral, or coronary use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M Whang -S

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

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