January 25, 2018

Cook Incorporated
Jessica Swafford
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47402

Re: K171264
Trade/Device Name: Royal Flush Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: December 22, 2017
Received: December 26, 2017

Dear Jessica Swafford:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K171264

Device Name
Royal Flush Catheter

Indications for Use *(Describe)*
The Royal Flush Catheters are intended for the delivery of contrast media to the peripheral and coronary vasculature, not including the neurovasculature.

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)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K171264 – 510(k) Summary

Royal Flush® Catheter
Traditional 510(k) Summary
21 CFR §807.92

Submitter Information

Applicant:	Cook Incorporated
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Contact:	Jessica P. Swafford
Email:	RegSubmissions@cookmedical.com
Contact Phone Number:	812-335-3575 ext. 104260
Contact Fax Number:	812-332-0281

Date Prepared:	25 January 2018

Device Information

Trade Name:	Royal Flush® Catheter
Common Name:	Angiographic Catheter
Classification Name:	Catheter, Intravascular, Diagnostic DQO (21 CFR §870.1200)

Predicate Device

The Royal Flush® Catheter, subject of this submission, is substantially equivalent to the primary predicate Slip-Cath® Beacon® Tip Catheter cleared under 510(k) number K122937 and the secondary predicate Mongoose® Pediatric Angiography Catheters cleared under 510(k) number K113819.

Reference Device

Cook has utilized the Sizing Catheters (K162448) as a reference device to support the biocompatibility of the subject device, the Royal Flush® Catheter.

Comparison to Predicates

It has been demonstrated that the subject Royal Flush® Catheter and the predicate devices are substantially equivalent in terms of intended use, duration of use, principles of operation, fundamental technological characteristics, and insertion method. The design, dimensions, manufacture, and materials of the subject device are either similar to the materials of the predicate devices or have been used in other cleared devices. The differences between the subject device and the predicate devices do not raise new questions of safety and effectiveness as demonstrated by performance and biocompatibility testing.

Device Description

The Royal Flush® Catheter subject of this submission is a sterile, single use device designed for use in angiographic procedures. The Royal Flush® Catheter is available in a 3.0 French size and is manufactured in lengths of 30 to 75 centimeters. Each configuration includes a luer lock adapter, connecting cap, and a single lumen shaft.

Intended Use

The Royal Flush® Catheters are intended for the delivery of contrast media to the peripheral and coronary vasculature, not including the neurovasculature.

Test Data

The Royal Flush® Catheter, subject of this submission, was subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests were conducted to ensure reliable design and performance:

- Biocompatibility testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogenicity, hemocompatibility, complement activation, and partial thromboplastin time) demonstrated that the device is biocompatible. In conformance with the applicable sections of AAMI ANSI ISO 10993-1:2009(R)2013, the predetermined acceptance criteria were met.

- Tensile Testing of the Hub to Shaft Joint – Testing verified that under proper clinical use of the catheter, the peak load value of the hub-to-shaft connection shall be in accordance with the applicable values of BS EN ISO 10555-1:2013, Annex B. The predetermined acceptance criterion was met.

- Tensile Testing of the Tip to Shaft Joint – Testing verified that under proper clinical use of the catheter, the peak load value of the tip-to-shaft connection shall be in accordance with the applicable values of BS EN ISO 10555-1:2013, Annex B. The predetermined acceptance criterion was met.

- Liquid Leakage Testing – Testing verified that under proper clinical use of the catheter, there shall be no liquid leakage when tested in accordance with BS EN ISO 10555-1:2013, Annex C. The predetermined acceptance criterion was met.

- Air Leakage Testing – Testing verified that under proper clinical use of the catheter, there shall be no air leakage when tested in accordance with BS EN ISO 10555-1:2013, Annex D. The predetermined acceptance criterion was met.

- Static Burst Testing – Testing successfully characterized the catastrophic failure pressure for the catheter is accordance with BS EN ISO 10555-1:2013, Annex F.

- Dimensional Verification Testing – Testing verified that the dimensional requirements of the subject devices are within a specified tolerance. The predetermined acceptance criteria were met.

- Tensile Testing of the Sideports – Testing verified that under proper clinical use of the catheter, the peak load values of the sideported area of the catheter shaft shall be in accordance with the applicable values of BS EN ISO 10555-1:2013, Annex B. The predetermined acceptance criterion was met.

- Hub Pressure Testing – Testing successfully characterized the hub pressure, when tested at maximum flow rate, and to verify that it does not exceed the static burst pressure.

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