April 25, 2019

Cook Incorporated
Reuben Lidster
Regulatory Affairs Specialist
P.O. Box 489, 750 Daniels Way
Bloomington, Indiana 47402

Re: K182071
Trade/Device Name: Multi-Sideport Catheter Infusion Set
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: March 14, 2019
Received: March 15, 2019

Dear Mr. Lidster:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

For Gregory O'Connell 2019.04.25 10:03:51 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182071

Device Name
Multi-Sideport Catheter Infusion Set

Indications for Use *(Describe)*
The Multi-Sideport Catheter Infusion Set is intended to administer infusions of various therapeutic solutions and contrast media into the peripheral vasculature.

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.

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K182071

510(k) Summary

Multi-Sideport Catheter Infusion Set

Traditional 510(k) Summary
21 CFR §807.92

Submitter Information

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Contact:	Reuben G. Lidster
Email:	RegSubmissions@CookMedical.com
Contact Phone Number:	812-335-3575 ext. 104866
Contact Fax Number:	812-332-0281

Date Prepared:	31 July 2018

Device Information

Trade Name:	Multi-Sideport Catheter Infusion Set
Common Name:	Continuous flush catheter
Classification Name:	Catheter, Continuous, Flush KRA (21 CFR §870.1210)

Predicate Device

The predicate device is the Merit Medical Systems Inc. Fountain Infusion System cleared under 510(k) number K991619. The predicate device is manufactured in a diameter of 5.0 French and in lengths of 45 - 135 centimeters. The catheter is compatible with a 0.035 inch wire guide. The infusion segment lengths are 5 - 50 centimeters and come with 40 to 400 sideports.

Reference Device

The reference device is the AngioDynamics SpeedLyser™ (K170258), which is available in

shorter lengths than the predicate.

Comparison to Predicate Device

The subject device, Multi-Sideport Catheter Infusion Set has a similar indication for use, duration of use, principles of operation, fundamental technological characteristics, and insertion method as the predicate device (K991619). Minor differences between the subject device and the predicate device include materials and dimensions. The differences between the subject device and the predicate device do not raise new questions of safety and effectiveness as demonstrated by the biocompatibility and performance testing.

Device Description

The Multi-Sideport Catheter Infusion Set is available in the 5.0 Fr size and is manufactured in lengths of 40, 65, 100 and 130 centimeters. The catheter is compatible with a 0.035 inch wire guide. The infusion segment lengths are 7, 15 or 20 centimeters and come with 14, 30 or 40 sideports. Each subject device set includes a catheter with a Luer lock adapter and a single lumen shaft, a tip occluder and Tuohy-Borst large bore clear plastic side adapter, and a dual check valve with a 1 ml syringe.

Intended Use

The Multi-Sideport Catheter Infusion Set is intended to administer infusions of various therapeutic solutions and contrast media into the peripheral vasculature.

Test Data

The Multi-Sideport Catheter Infusion Set, subject of this submission, was subjected to the applicable testing listed below to assure reliable design and performance under the testing parameters. Performance and biocompatibility testing were conducted in accordance with applicable standards and FDA guidance documents to confirm the reliable performance of critical device characteristics.

- Biocompatibility testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, pyrogenicity, subchronic toxicity, genotoxicity, implantation, hemocompatibility, complement activation, partial thromboplastin time and *in vivo* thrombogenicity) demonstrated that the subject device is biocompatible for the intended use. In conformance with the applicable sections of ANSI AAMI ISO 10993- 1:2009(R)2013, the predetermined acceptance criteria were met.
- Air Leakage Testing – Testing verified that, under proper clinical use of the

subject device, there will be no air leakage when tested in accordance with the methods described in BS EN ISO 10555-1:2013, Annex D. The predetermined acceptance criterion was met.

- Compatibility Testing – Testing verified that the compatibility requirements of the subject device are within a specified tolerance. The predetermined acceptance criteria were met.
- Corrosion Testing - Tested in accordance with Annex B of ISO 11070:2014. The predetermined acceptance criteria were met.
- Dimensional Verification Testing – Testing was completed in accordance with an approved study protocol. The predetermined acceptance criteria were met.
- Liquid Leakage Testing – Testing verified that, under proper clinical use of the subject device, there will be no liquid leakage when tested in accordance with the methods described in BS EN ISO 10555-1:2013, Annex C. The predetermined acceptance criterion was met.
- Tuohy Stress Cracking – Testing verified the requirements of no signs of leakage or stress cracking when tested in accordance with ISO 80369-7:2016. The predetermined acceptance criteria were met.
- Tensile Testing of the Hub-to-Shaft Bond – Testing verified that, under proper clinical use of the subject device, the peak load value of the hub-to-shaft connection is in accordance with the methods of BS EN ISO 10555-1:2013, Annex B. The predetermined acceptance criterion was met.
- Tensile Testing of the Marker Band to Shaft Bond – Testing was completed in accordance with an approved study protocol. The predetermined acceptance criterion was met.
- Tensile Testing of the Sideported Area – Testing verified that, under proper clinical use of the subject device, the peak load value of the sideported area of the shaft is in accordance with the methods of BS EN ISO 10555-1:2013, Annex B. The predetermined acceptance criterion was met.
- Radiopacity Testing - The results verified, under the proper clinical use of the subject device, the test articles were visible when imaged under fluoroscopy. The predetermined acceptance criterion was met.

- Simulated Use Testing – The results verified, under simulated clinical use of the subject device, the test articles can be loaded, advanced, flushed and withdrawn as intended, without kinks or material separation. The predetermined acceptance criteria were met.

Conclusion

The results of testing support a conclusion that the Multi-Sideport Catheter Infusion Set met the design input requirements based on the intended use and support the conclusion that the modifications do not raise new questions of safety or effectiveness. The results of these tests support a determination of substantial equivalence to the predicate device, the Merit Medical Fountain Infusion Catheter (K991619).