April 4, 2019

Cook Incorporated
Rebecca Odulio
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K182399
Trade/Device Name: Park Blade Septostomy Catheter
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy Catheter
Regulatory Class: Class II
Product Code: DXF
Dated: October 19, 2018
Received: October 22, 2018

Dear Rebecca Odulio:

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); 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,

Rachel E. Neubrander -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182399

Device Name
Park Blade Septostomy Catheter

Indications for Use *(Describe)*

The Park Blade Septostomy Catheter is intended to enlarge interatrial openings. The device can also be used when balloon atrial septostomy is insufficient or unsuccessful, particularly in older infants and children with a thickened atrial septum. Normally, the existing interatrial opening is used for this procedure. However, if the interatrial septum is intact, the procedure can be performed in conjunction with a transseptal technique.

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.

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

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510(k) Summary: K182399

Submitted By: Rebecca Odulio (Li-chun Liu)
Cook Incorporated
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Bloomington, IN 47404
Phone: (812) 335-3575 x104673
Fax: (812) 332-0281
Date Prepared: August 31, 2018

Device:

Trade Name:	Park Blade Septostomy Catheter
Common Name:	Septostomy Catheter
Classification Name:	Catheter, Septostomy DXF (21 CFR §870.5175)
Product classification:	Class II
Review Panel:	Cardiovascular

Indications for Use:

The Park Blade Septostomy Catheter is intended to enlarge interatrial openings. The device can also be used when balloon atrial septostomy is insufficient or unsuccessful, particularly in older infants and children with a thickened atrial septum. Normally, the existing interatrial opening is used for this procedure. However, if the interatrial septum is intact, the procedure can be performed in conjunction with a transseptal technique.

Predicate Device:

The predicate device, the Blade Septostomy Catheter, was cleared for commercial distribution under 510(k) number K801031, on July 28, 1980.

Comparison to Predicate Device:

It has been demonstrated that the Park Blade Septostomy Catheter is identical to the predicate device (K801031) in terms of intended use, principles of operation, basic technological characteristics, and similar in materials of construction to the predicate device. Additional device dimensions and material changes have been included for the subject device as compared to the

predicate device. The safety and effectiveness of the subject device modifications are supported by performance and biocompatibility testing.

Device Description:

The Park Blade Septostomy Catheter is a radiopaque polyethylene catheter with a distal tip section made of a stainless-steel cannula and a proximal end section consisting of a pin vise, a gasket, and a Y sidearm adapter. The distal stainless-steel cannula contains a stainless-steel blade that is linked to a lever, which allows the distal end to form a triangle. The Park Blade Septostomy Catheter is manufactured in 5.7 or 7.3 French sizes. The catheter working length measures either 65 or 85 centimeters from the distal tip to the distal end of the shrink tube. The blade lengths for the 5.7 French catheters are either 9.4 or 13.4 millimeters; for the 7.3 French size catheter, the blade measures 20.0 millimeters.

Test Data:

The following tests were performed to demonstrate that the Park Blade Septostomy Catheter met applicable design and performance requirements and support a determination of substantial equivalence.

- Biocompatibility Testing – Testing was performed in accordance with ISO 10993-1:2009. The pre-determined acceptance criteria were met.
- Radiopacity Testing – Radiopacity testing was performed in accordance with the qualitative evaluation described in ASTM F640-12 and BS EN ISO 10555-1. The pre-determined acceptance criteria were met.
- Tensile Testing – Testing was performed in accordance with BS EN ISO 10555-1. The pre-determined acceptance criteria were met.
- Corrosion Testing – Testing demonstrated, when tested in accordance with BS EN ISO 10555-1, the device revealed no signs of corrosion that would affect functional performance. The pre-determined acceptance criteria were met.
- Dimensional and Blade Activation Verification – Testing was performed in accordance with design input specifications. The pre-determined acceptance criteria were met.

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