November 30, 2018

Cook Incorporated
Johnathan Liu
Regulatory Affairs Team Lead
750 Daniels Way
Bloomington, Indiana 47404

Re: K180792
Trade/Device Name: Arterial Pressure Monitoring Set/Tray
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: October 19, 2018
Received: October 22, 2018

Dear Johnathan Liu:

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,

Stephen C. Browning -S5

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

Device Name
Arterial Pressure Monitoring Set/Tray

Indications for Use (Describe)
The Arterial Pressure Monitoring Set/Tray is intended for arterial blood pressure monitoring and blood sampling in adult and pediatric patients.
- 5.0 French catheters are intended for patients aged 12 years and older

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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Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
Submitted By:
Submission: Traditional 510(k) Premarket Notification
Applicant: Cook Incorporated
Applicant Address: Cook Incorporated
750 Daniels Way
Bloomington, IN 47404
Contact: Johnathan Liu
Chelsea Woods
Secondary Contact: Andrew Breidenbach, PhD, RAC
Email: regsubmissions@cookmedical.com
Contact Phone Number: (812) 335-3575 x104509
Contact Fax Number: (812) 332-0281

Device Information:
Trade Name: Arterial Pressure Monitoring Set/Tray
Common Name: Catheter, Intravascular, Diagnostic
Classification Name: Diagnostic intravascular catheter
Regulation: 21 CFR §870.1200
Product Code: DQO
Device Class: II
Classification Panel: Cardiovascular

Predicate Device:
The Arterial Pressure Monitoring Set/Tray is substantially equivalent to the following device: Cook Pressure Monitoring Catheter (K002254, Cook Incorporated) cleared on March 16, 2001.
Device Description:
The Arterial Pressure Monitoring Set/Tray consists of a pressure monitoring catheter, wire guide, access needle, and syringe. The catheter is inserted into the vasculature using the Seldinger technique. The subject device is sterilized by ethylene oxide and intended for one-time use. The subject device catheter is a single lumen intravascular catheter manufactured from nylon tubing and is designed with a pre-molded proximal winged hub. The catheter is 5.0 French with a length of 15 centimeters and has an endhole diameter of 0.035 inches. Additionally, the catheter is manufactured with one-centimeter incremental ink markings along the shaft. The wire guide is manufactured from stainless steel, has an outer diameter of 0.035 inches, and a length of 50 centimeters. The access needle is manufactured from stainless steel. Additional set configurations may contain convenience accessories, including lidocaine, PVP ointment, silk suture, Monoject needles, thumb scalpel, gauze, drapes, a filter straw, and ChloraPrep antiseptic.

Indications for Use:
The Arterial Pressure Monitoring Set/Tray is intended for arterial blood pressure monitoring and blood sampling in adult and pediatric patients.

- 5.0 French catheters are intended for patients aged 12 years and older

Comparison to Predicate Device:
The Arterial Pressure Monitoring Set/Tray is substantially equivalent to the predicate device, Cook Pressure Monitoring Catheter (K002254), in that these devices are identical in intended use, principle of operation, catheter design (single lumen, straight tip), and packaging. The differences between the subject device and the predicate device, including pediatric indication, materials, and dimensions, do not raise different questions of safety and/or effectiveness when compared to the predicate. The substantial equivalence comparison of the subject device to the predicate is provided in the table below.
<table>
<thead>
<tr>
<th>PREDICATE DEVICE</th>
<th>SUBJECT DEVICE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td>The Arterial Pressure Monitoring Set/Tray is intended for arterial blood pressure monitoring and blood sampling in adult and pediatric patients. - 5.0 French catheters are intended for patients aged 12 years and older.</td>
</tr>
<tr>
<td><strong>Device is for One-time use</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Catheter Placement Method</strong></td>
<td>IDENTICAL TO PREDICATE</td>
</tr>
<tr>
<td><strong>Catheter</strong></td>
<td>IDENTICAL TO PREDICATE</td>
</tr>
<tr>
<td><strong>Shaft Material</strong></td>
<td>Polyurethane</td>
</tr>
<tr>
<td><strong>Hub Material</strong></td>
<td>Polyurethane</td>
</tr>
<tr>
<td><strong>Outer Diameter</strong></td>
<td>3.0 French</td>
</tr>
<tr>
<td><strong>Length</strong></td>
<td>2.5, 5.0, 7.5, 8.0, 12.0, 22.0 cm</td>
</tr>
<tr>
<td><strong>Number of Lumens</strong></td>
<td>Single Lumen</td>
</tr>
<tr>
<td><strong>Distal Tip Design</strong></td>
<td>Straight Tip</td>
</tr>
<tr>
<td><strong>Ink Markings</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Packaging</strong></td>
<td>Tray w/ Tyvek lidstock</td>
</tr>
<tr>
<td><strong>Sterilization Method</strong></td>
<td>EtO</td>
</tr>
<tr>
<td><strong>Sterility Assurance Level</strong></td>
<td>$10^6$</td>
</tr>
</tbody>
</table>
Technological Characteristics:
The subject device, Arterial Pressure Monitoring Set/Tray was subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests have been conducted to ensure reliable design and performance under the specified testing parameters:

Performance Testing:
- Catheter Shaft Tensile (Aged) – The peak tensile load for the shaft section of the catheter shall be greater than or equal to 10 N in accordance with BS EN ISO 10555-1:2013. The acceptance criterion was met.
- Catheter Hub-to-Shaft Tensile (Aged) – The peak tensile load for the hub-to-shaft section of the catheter shall be greater than or equal to 10 N in accordance with BS EN ISO 10555-1:2013. The acceptance criterion was met.
- Catheter Liquid Leakage (Aged) – No part of the catheter shall leak liquid when tested in accordance with Annex C of BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Air Leakage (Aged) – No air shall enter the hub when tested in accordance with Annex D of BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Kink Length (Aged) – The catheter shall not kink (flow rate reduced by 50%) at a specified kink (circumferential) length when tested in accordance with Annex B of BS EN 13868. The acceptance criterion was met.
- Catheter Gravity Flow Rate (Time-Zero) – The flow rate shall be a minimum of 90% of the flow rate stated by the manufacturer when tested in accordance with Annex E of BS EN ISO 10555-1. The acceptance criterion was met.
- Visual Inspection & Dimensional Analysis (Aged) – Test was conducted to demonstrate that the catheter dimensions are within the specified tolerances and the catheter and wire guide are compatible.

Biocompatibility Testing:
- Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, material-mediated pyrogenicity, subacute/subchronic toxicity, genotoxicity, implantation, and hemocompatibility were performed to ensure the biocompatibility of the subject device set.
Conclusion:
The results of these tests confirm that the Arterial Pressure Monitoring Set/Tray meets the design input requirements based on the intended use and support the conclusion that this device does not raise different questions of safety and/or effectiveness and is substantially equivalent to the predicate device, the Cook Pressure Monitoring Catheter (K002254).