December 19, 2018

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

Re: K180846
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: November 26, 2018
Received: November 27, 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. However, you are responsible to determine that the medical devices you use as components in the tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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

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)*

K180846

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.

- 2.5 French catheters are intended for patients from birth and older
- 3.0 and 4.0 French catheters are intended for patients 1 year 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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2.0 510(k) SUMMARY

K180846
Arterial Pressure Monitoring Set/Tray
21 CFR §807.92
Date Prepared: December 17, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated
	750 Daniels Way
	Bloomington, IN 47404
Primary Contact:	Johnathan Liu
Secondary Contact:	Chelsea Woods
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 is comprised of a pressure monitoring catheter, wire guide, entry access needle, and syringe. Certain sets are also available with a dilator and/or other convenience components. The catheter is manufactured from polyurethane, ethylene-vinyl acetate, or polyethylene tubing and is designed with a pre-molded winged hub. Catheters are manufactured 2.5, 3.0, and 4.0 French in size with endhole diameters of 0.015, 0.018, and 0.021 inches, respectively. The wire guide is manufactured from stainless steel coils, a safety wire, a mandril wire, and All-State solder. The access needle is manufactured from stainless steel. The dilator is manufactured from polyethylene and has a pre-molded proximal hub. Other convenience accessories include syringes, lidocaine solution, PVP ointment, antiseptic, Monoject needles, a scalpel, gauze, drapes, and needle holders. The Arterial Pressure Monitoring Set/Tray is sterilized by ethylene oxide and intended for one-time use.

Indications for Use:

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

- 2.5 French catheters are intended for patients from birth and older
- 3.0 and 4.0 French catheters are intended for patients 1 year and older

Comparison to Predicate Device:

The Arterial Pressure Monitoring Set/Tray and the predicate device, Cook Pressure Monitoring Catheter (K002254), are substantially equivalent in that these devices are identical in intended use, principle of operation, and fundamental technologies. Additionally, the subject device has similar materials and dimensions as the predicate device. The differences between the subject device and the predicate device, including pediatric indication, materials, and other dimensions do not raise any new issues of safety and/or effectiveness. The substantial equivalence comparison of the subject device to the predicate is provided in the table below.

	PREDICATE DEVICE	SUBJECT DEVICE
	Cook Pressure Monitoring Catheter (K002254)	**Arterial Pressure Monitoring Set/Tray**
Regulation	21 CFR §870.1200	IDENTICAL TO PREDICATE
Product Code	DQO – Catheter, Intravascular, Diagnostic	IDENTICAL TO PREDICATE
Classification	II	IDENTICAL TO PREDICATE
Indications for Use	The Cook Pressure Monitoring Catheter is used for arterial pressure monitoring and blood sampling. It is provided sterile in peel-open packages and intended for one-time use.	The Arterial Pressure Monitoring Set/Tray is intended for arterial blood pressure monitoring and blood sampling in adult and pediatric patients. - 2.5 French catheters are intended for patients from birth and older - 3.0 and 4.0 French catheters are intended for patients 1 year and older
Device is for One-time use	Yes	IDENTICAL TO PREDICATE
Catheter Insertion Method	Percutaneously via Seldinger technique	IDENTICAL TO PREDICATE
Catheter Insertion Site	Not specified	Radial, Brachial, Dorsalis Pedis, Femoral, Posterior Tibial Arteries
Catheter Shaft Material	Polyurethane	Polyethylene Ethylene-Vinyl Acetate Polyurethane
Catheter Hub Material	Polyurethane	Polyethylene Polyurethane
Catheter Outer Diameter	2.5, 3.0, 4.0, 5.0 French	2.5, 3.0, 4.0 French
Catheter Length	2.5, 5.0, 7.5, 8.0, 12.0, 22.0 cm	2.5, 4.0, 5.0, 6.0, 8.0, 12.0 cm
Catheter Lumen Design	Single Lumen	IDENTICAL TO PREDICATE
Catheter Distal End	Straight Tip	IDENTICAL TO PREDICATE
Dilator Shaft Material	Polypropylene	Polyethylene
Wire Guide Material	Stainless Steel	Stainless Steel All-State Solder
Wire Guide Diameter	0.015, 0.018, 0.021, 0.035 inch	IDENTICAL TO PREDICATE
Packaging	Tray w/ Tyvek Lidstock	IDENTICAL TO PREDICATE
Sterilization	EtO	IDENTICAL TO PREDICATE
Sterility Assurance Level	10^{-6}	IDENTICAL TO PREDICATE

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 (Time Zero and Aged) – The peak tensile load for the shaft section of the catheter shall be greater than or equal to 5 N for 2.5 and 3.0 Fr catheters, and 10 N for 4.0 and 5.0 Fr catheters in accordance with BS EN ISO 10555-1:2013. The acceptance criteria were met.
- Catheter Hub-to-Shaft Tensile (Time Zero and Aged) – The peak tensile load for the hub-to-shaft section of the catheter shall be greater than or equal to 5 N for 2.5 and 3.0 Fr catheters, and 10 N for 4.0 and 5.0 Fr catheters in accordance with BS EN ISO 10555-1:2013. The acceptance criteria were met.
- Catheter Liquid Leakage (Time Zero and 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 (Time Zero and 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 (Time Zero and Aged) – The catheter shall not kink (flowrate 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 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 Verification, Compatibility (Time-Zero, Aged) – Test was conducted to demonstrate that the catheter dimensions are within the specified tolerances and the catheter and wire guide are compatible.
- Wire Guide Corrosion (Time-Zero) – The wire guide shall show no evidence of corrosion that could affect the functional performance when tested in accordance with Annex B of BS EN ISO 11070:2014. The acceptance criterion was met.

- Wire Guide Fracture (Time-Zero) – The wire guide shall not fracture when wound around an approximate former in accordance with Annex F of BS EN ISO 11070. The acceptance criterion was met.
- Wire Guide Flex (Time-Zero) – The wire guide shall show no signs of defects or damage, including flaking or material loss when tested in accordance with Annex G of BS EN ISO 11070. The acceptance criterion was met.
- Wire Guide Tensile (Time-Zero) – The peak tensile load to failure shall be greater than or equal to 5 N for wire guides with an outside diameter greater than or equal to 0.55 mm and less than 0.75 mm, and 10 N for wire guides with an outside diameter greater than or equal to 0.75 mm in accordance with Annex H of BS EN ISO 11070. The acceptance criterion was met.
- Dilator Hub-to-Shaft Tensile (Time Zero and Aged) – The peak tensile load for the hub-to-shaft section of the dilator shall be greater than or equal to 5 N for 3.0 Fr dilators and 10 N for 3.5, 4.0, 5.0, and 5.5 Fr dilators, in accordance with BS EN ISO 11070. The acceptance criterion was met.

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.

Sterilization Testing:

- Per ISO 10993-1 Residual levels of ethylene oxide (EO) and ethylene chlorohydrin (ECH) have been evaluated and verified to be no greater than the maximum limits as specified in ANSI/AAMI/ISO 10993-7:2008(R)2012: Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.

Packaging Testing following simulated distribution:

- Visual Inspection – No package shall display damage that will compromise sterility of its contents. The acceptance criterion was met.
- Destructive Inspection – The components inside the package shall show no signs of damage that would interfere with the performance of the product. The acceptance criterion was met.
- Bubble Test – The package shall show no signs of pin holes or imperfect seals indicated by bubbles created from the pressurized air leaking into the surrounding solution. The acceptance criterion was met.

- Seal Strength Test – Per EN 868-5:1999, the seal strength shall not be less than 1.2N per 15 mm (0.46 lbf/in). For additional confidence, the mean seal force - 3 σ shall meet or exceed 0.50 lbf/in. The acceptance criterion was met.

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).