February 22, 2018

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

Re: K171994
Trade/Device Name: Silicone Peripherally Inserted Central Venous Catheter Set/Tray
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: January 22, 2018
Received: January 23, 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. 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K171994

Device Name

Silicone Peripherally Inserted Central Venous Catheter Set/Tray

Indications for Use *(Describe)*

The Silicone Peripherally Inserted Central Venous Catheter Set/Tray is intended for delivery of whole blood or blood products, drug administration and blood sampling.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

2.0 510(k) SUMMARY

K171994
Silicone Peripherally Inserted Central Venous Catheter Set/Tray
21 CFR §807.92(c)
Date Prepared: February 21, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact:	Johnathan Liu
Email:	regsubmissions@cookmedical.com
Contact Phone Number:	(812) 335-3575 x104509
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	**Silicone Peripherally Inserted Central Venous Catheter Set/Tray**
Common Name:	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days
Classification Name:	Percutaneous, implanted, long-term intravascular catheter
Regulation:	21 CFR §880.5970
Product Code:	LJS
Device Class:	II
Classification Panel:	General Hospital

Predicate Devices:

The Silicone Peripherally Inserted Central Venous Catheter Set/Tray is substantially equivalent to the following:

- Primary Predicate: Medcomp Vascu-PICC™ Catheter cleared on April 11, 2003 (K030270).
- Secondary Predicate: Cook Spectrum Silicone Catheter cleared on May 30, 2003 (K021557).

Device Description:

The Silicone Peripherally Inserted Central Venous Catheter Set/Tray is composed of a peripherally inserted central venous catheter, obturator, wire guide, Peel-Away® introducer, access needle, syringe, catheter securement device, thumb scalpel, drape, and tape measure. Additional set configurations may also include a dilator, gauze, Lidocaine, Monoject needles, and other convenience accessories. The catheter is available in a single (3.0, 4.0, 5.0 French) or dual lumen (7.0 French) configuration with lengths of 50 and 60 centimeters. The catheter shaft is manufactured from silicone radiopaque tubing, which is connected to a silicone winged manifold. Proximally, the winged manifold is attached to one or two silicone extension tubes with a pre-molded acetal hub. Additionally, removable polypropylene clamps are attached to each extension tube. The obturator is manufactured from stainless steel and has a hydrophilic coating. It is designed to fit in the catheter and is manufactured with a proximal Luer hub that can be locked into the proximal hub of the corresponding catheter. The wire guide is manufactured with either stainless steel or a nitinol mandril with a platinum tip. The introducer is composed of a radiopaque tetrafluoroethylene (TFE) Peel-Away® sheath and a polyethylene dilator matched for transitional fit. The Silicone Peripherally Inserted Central Venous Catheter Set/Tray is sterilized by ethylene oxide and intended for one-time use.

Indications for Use:

The Silicone Peripherally Inserted Central Venous Catheter Set/Tray is intended for delivery of whole blood or blood products, drug administration and blood sampling.

Comparison to Primary Predicate Device:

The Silicone Peripherally Inserted Central Venous Catheter Set/Tray and the primary predicate device, the Medcomp Silicone Vascu-PICC™ Catheter (K030270), are substantially equivalent in that these devices are identical in principles of operation and fundamental technologies. Through performance testing the subject device and predicate device have demonstrated substantial equivalence. The substantial equivalence comparison of the subject device to the predicate is summarized in the table below.

	PRIMARY PREDICATE DEVICE	SUBJECT DEVICE
	Medcomp Silicone Vascu-PICC™ Catheter (K030270)	**Silicone Peripherally Inserted Central Venous Catheter Set/Tray**
Regulation	880.5970	Identical
Product Code	LJS Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days	Identical
Classification	II	Identical
Indications for Use	For long term central venous catheterization or prolonged intravenous administration of fluids, medications and/or when nutritional therapy is prescribed. The catheter may be inserted via basilica or cephalic vein.	Silicone Peripherally Inserted Central Venous Catheter (PICC) Sets are intended for delivery of whole blood or blood products, drug administration and blood sampling.
Device is for One-time Use	Yes	Identical
Catheter Insertion Method	Percutaneous via Seldinger	Identical
Catheter Tip Target Anatomy	Superior vena cava (SVC)	Identical
Catheter Tip Location Confirmation Method	X-ray	Identical
Catheter Shaft Material	Radiopaque Silicone	Identical
Catheter Outer Diameter	Single: 3.0, 4.0, 5.0 Fr Dual: 4.0, 5.0, 6.0 Fr	Single: 3.0, 4.0, 5.0 Fr Dual: 7.0 Fr
Catheter Length	60 cm	50, 60 cm
Catheter Lumen Number	Single, Dual	Identical
Catheter Lumen Configuration	Unknown	Single: Round Dual: D-shaped
Catheter Distal End Configuration	Straight	Identical
Incremental Markings	5 cm increments	None
Extension Tube Clamps	Yes	Identical
Packaging	Tray	Tray with Tyvek Lidstock
Sterilization Method	EtO	Identical
Sterility Assurance Level	Unknown	10^{-6}
Components and Accessories	PICC w/ Stylet Wire Guide Peelable Sheath Introducer Needle Syringe Scalpel Tape Measure Catheter Securement Device Drape Lidocaine Safety Needles Gauze Chlorhexidine Needle Stick Pad	PICC w/ Obturator Wire Guide Peel-Away Introducer Dilator Needle Syringe Thumb Scalpel Tape Measure Catheter Securement Device Drape Lidocaine Monoject Needles Gauze ChloraPrep Needle Holder Female Luer-locks Suture with Needle PVP Ointment CSR Wrap

Comparison to Secondary Predicate Device:

The Silicone Peripherally Inserted Central Venous Catheter Set/Tray and the secondary predicate device, Cook Spectrum Silicone Catheter (K021557), are substantially equivalent in that these devices are identical in principles of operation and fundamental technologies. The substantial equivalence comparison of the subject device to the predicate is summarized in the table below.

	SECONDARY PREDICATE DEVICE	**SUBJECT DEVICE**
	Cook Spectrum® Silicone Catheter (K021557)	**Silicone Peripherally Inserted Central Venous Catheter Set/Tray**
Regulation	880.5970	Identical
Product Code	LJS Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days	Identical
Classification	II	Identical
Indications for Use	The Cook Spectrum Silicone Catheter is used for intravenous administration of nutrient fluids, chemotherapeutic agents and other drugs for therapy, blood sampling, blood delivery, and venous pressure monitoring. The catheter is impregnated with the antimicrobials minocycline and rifampin to help provide protection against catheter-related bloodstream infections (CRBSI). It is not intended to be used as a treatment for existing infections. Catheters are available in single and double lumen PICC; and single, double and triple lumen CVC.	Silicone Peripherally Inserted Central Venous Catheter (PICC) Sets are intended for delivery of whole blood or blood products, drug administration and blood sampling.
Device is for One-time Use	Yes	Identical
Catheter Insertion Method	Percutaneous via Seldinger	Identical
Catheter Tip Target Anatomy	Superior vena cava (SVC)	Identical
Catheter Tip Location Confirmation Method	X-ray	Identical
Catheter Shaft Material	Radiopaque Silicone	Identical
Antimicrobial Material	Minocycline and Rifampin	None
Catheter Outer Diameter	Single: 4.0, 5.0 Fr Dual: 6.0, 7.0 Fr	Single: 3.0, 4.0, 5.0 Fr Dual: 7.0 Fr
Catheter Length	50, 60 cm	Identical
Catheter Lumen Number	Single, Dual	Identical
Catheter Lumen Configuration	Single: Round Dual: D-shaped	Identical
Catheter Distal End Configuration	Straight	Identical
Incremental Markings	None	Identical
Extension Tube Clamps	Yes	Identical
Packaging	Tray with Tyvek Lidstock	Identical
Sterilization Method	EtO	Identical
Sterility Assurance Level	10^{-6}	Identical

Components and Accessories	PICC w/ Obturator Wire Guide Peel-Away Introducer Dilator Needle Syringe Thumb Scalpel Tape Measure Catheter Securement Device Drape Lidocaine Monoject Needles Gauze ChloraPrep Needle Holder Female Luer-locks Suture with Needle PVP Ointment CSR Wrap	Identical

Cook Spectrum Silicone Catheter, cleared under K021557 is being used as a secondary predicate device for having the same technology as the subject device of not having incremental markings on the catheter shaft. The labeling and instructions for use for K021557 and the subject device are similar and both state “catheter tip position should be verified by x-ray and monitored on a routine basis with periodic lateral-view x-ray”.

Technological Characteristics:

The subject device, the Silicone Peripherally Inserted Central Venous Catheter Set/Tray, was subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters:

<u>Bench Testing (including time zero and applicable three year accelerated aged testing)</u>

- Catheter
  - Tensile - Testing performed on the various joints of the catheter per applicable ISO standards demonstrated that the devices met the acceptance criteria.
  - Liquid Leakage - Testing performed on the catheters demonstrated that the catheters did not leak.
  - Air Leakage - Testing demonstrated the catheters meet the air leak requirements of BS EN ISO 10555-1.
  - Kink Radius - Testing demonstrated that flow rate was not impacted during kinking of the catheter.

- Gravity Flow Rate - Testing demonstrated that the catheters have an acceptable flow rate for the clinical application.
- Radiopacity - Testing performed demonstrated that the devices are visible in the radiographic image.
- MR Testing - Testing in accordance with ASTM F2503 showed that the catheters are MR Conditional.
- Dimensional Verification - Testing performed demonstrated that the test specimens' dimensions are within the specified tolerances and markings are clearly marked on shrink tube.
- Compatibility - Testing performed demonstrated that the PICC set components are compatible.

- Obturator
  - Corrosion - Tested in accordance with Annex B of ISO 11070:2014. The pre-determined acceptance criteria were met.
  - Hub-to-Wire Tensile - Testing performed on the joint of hub and wire demonstrated that the devices met the acceptance criteria.
- Wire Guide
  - Corrosion - Tested in accordance with Annex B of ISO 11070:2014. The pre-determined acceptance criteria were met.
  - Tensile - Tested in accordance with the applicable values of BS EN ISO 11070:2014, Annex H. The pre-determined acceptance criteria were met.
  - Fracture - Tested in accordance with Annex F of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
  - Flex - Tested in accordance with the Annex G of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Peel-Away Introducer
  - Hub-to-Shaft Tensile - Testing performed on the joint of hub and wire demonstrated that the devices met the acceptance criteria.

<u>Biocompatibility Testing:</u>

- 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 demonstrated the biocompatibility of the subject devices.

Sterility Testing and Shelf-Life:

- Sterilization Validation: The established method used to validate the sterilization cycle is consistent with the half-cycle method as described in ISO 11135-1:2007. In addition, Cook complies with BS EN 556-1:2001.
- Sterility Assurance Level (SAL): 10^{-6}
- Sterilization Method: The subject device is sterilized using Ethylene Oxide (EO) gas in a fixed chamber.
- EO Residual Level: In accordance with ISO 10993-7:2008, the maximum allowable limits for EO and ECH was less than or equal to the suggested sterilant residual limits for a permanent contact device (> 30 days):
    - EO (Average Daily Dose): 4 mg
    - ECH (Average Daily Dose): 9 mg
- Bacterial Endotoxin Test Method (LAL): Endotoxin testing is performed with the maximum testing limit being 20 EU/device, as recommended by the sterility guidance (*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*) for blood contacting devices.
- Shelf-Life: The three-year shelf-life of the subject device is based on successful testing of performance characteristics on devices aged to a minimum of three-year equivalency by accelerated methods.

Conclusion:

The results of these tests confirm that the Silicone Peripherally Inserted Central Venous Catheter Set/Tray meets the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety or effectiveness and is substantially equivalent to the primary predicate device, Medcomp Silicone Vascu-PICC™ Catheter (K030270), and the secondary predicate device, Cook Spectrum Silicone Catheter (K021557).