February 3, 2023

Cook Advanced Technologies
Matthew Waninger
VP, Product Approval Processes
1400 Cumberland Avenue
West Lafayette, Indiana 47906

Re: K223648
Trade/Device Name: Cook® Spectrum® 2 MRC Central Venous Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: December 6, 2022
Received: December 7, 2022

Dear Matthew Waninger:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Wolloscheck, PhD
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K223648

Device Name
Cook® Spectrum® 2 MRC Central Venous Catheter

Indications for Use *(Describe)*
The Cook® Spectrum® 2 MRC Central Venous Catheter is indicated to provide short-term (<30 days) central venous access intended for:

- Continuous or intermittent drug infusion
- Central venous blood pressure monitoring (CVP)
- Acute hyperalimentation
- Blood sampling
- Delivery of whole blood or blood products
- Simultaneous, separate infusion of drugs and
- Power injection of contrast media (max 300 psi).

The activity of the antimicrobial agents, minocycline, rifampin and chlorhexidine is located at the internal and external catheter surfaces and is not intended for treatment of existing infections. This combination of antimicrobials has been shown to reduce microbial colonization of the catheter. The effectiveness was evaluated using in vitro methods; no correlation between in vitro and clinical outcome has currently been ascertained. Controlled studies of this product have not been conducted in pregnant women, pediatric or neonatal patients. The benefits of the use of this catheter should be weighed against any possible risk. Consider CDC Guidelines and institutional protocols for catheter exchange.

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 ADVANCED TECHNOLOGIES
1400 CUMBERLAD AVENUE
WEST LAFAYETTE, IN 47906 USA
PHONE: 765.269.4190 FAX: 765.463.0570
WW.COOKMEDICAL.COM

K223648 - 510K Summary

1. **Date of Preparation**: February 3, 2023

2. **Submitter Name:** Cook Advanced Technologies
   1400 Cumberland Avenue
   West Lafayette, IN 47906

3. **Contact Person:** Matthew S. Waninger
   Vice President
   Product Approval Processes
   Email: mwaninger@medinstitute.com
   Phone Number: (765) 269-4190
   Fax Number: (765) 463-0570

4. **Trade Name:** Cook® Spectrum® 2 MRC Central Venous Catheter
   Regulation Name: Intravascular catheter
   Common Name: Short-Term less than 30 days Therapeutic, Intravascular Catheter
   Regulation Number: 21 CFR 880.5200
   Product Code: FOZ
   Device Class: II

   Predicate Device: K081113, Cook® Spectrum®/Spectrum® Glide Central Venous Catheter

   Reference Device: K071538, ARROWg+ard Blue PLUS® Central Venous Catheter

5. Device Description:

The Cook® Spectrum® 2 MRC Central Venous Catheter is a single-use, antibiotic impregnated, antimicrobial coated, power injectable catheter that is percutaneously inserted into the vasculature using the Seldinger technique, and advanced over a wire guide until its tip is positioned above the superior vena cava-right atrium (SVC-RA) junction within the lower third of the SVC. The Cook® Spectrum® 2 MRC Central Venous Catheter, 7 Fr triple lumen CVC, is made from an aliphatic polyether-based polyurethane catheter shaft with a radiopaque constituent and a bonded soft distal tip. The catheter shaft is impregnated with Spectrum® (minocycline, rifampin) antimicrobial agents and coated with chlorhexidine antiseptic. The Cook® Spectrum® 2 MRC Central Venous Catheter is not intended for treatment of existing infections in patients; the presence of the three antimicrobial agents has been shown to reduce microbial colonization of the catheter. The antimicrobial activity of these agents is localized to the internal and external catheter surfaces. The working length (15, 20, or 25 cm) of the catheter is measured from distal tip to the double bar line approximately 1.5 cm distal to the manifold. The catheter shaft features centimeter length markings. The proximal portion of the Cook® Spectrum® 2 MRC Central Venous Catheter, like the predicate catheter, has three extension tubes with injection-molded Luer hubs connected to a manifold. The injection-molded manifold with suture wings serves as the transition point for lumens of the extension tubes into each lumen of the catheter shaft. All three lumens are power injectable; the maximum flow rate is labeled on the hub of each extension tube.

6. Indications for Use:

	Predicate Device Cook® Spectrum®/Spectrum® Glide Central Venous Catheter K081113	**Subject Device** Cook® Spectrum® 2 MRC Central Venous Catheter K223648
Indication for Use	The Cook® Spectrum®/ Spectrum® Glide Central Venous Catheter is used for: • Continuous or intermittent drug infusions • Central venous blood pressure monitoring (CVP) • Acute hyperalimentation • Blood sampling	The Cook® Spectrum® 2 MRC Central Venous Catheter is indicated to provide short-term (<30 days) central venous access intended for: • Continuous or intermittent drug infusion • Central venous blood pressure monitoring (CVP) • Acute hyperalimentation

	Predicate Device Cook® Spectrum®/Spectrum® Glide Central Venous Catheter K081113	**Subject Device** Cook® Spectrum® 2 MRC Central Venous Catheter K223648
	• Delivery of whole blood or blood products • Power injection of contrast media	• Blood sampling • Delivery of whole blood or blood products • Simultaneous, separate infusion of drugs and • Power injection of contrast media (max 300 psi).
Indication for Use (continued)	The activity of the antimicrobial agents, minocycline and rifampin, is localized at the internal and external catheter surface, and helps to provide protection against catheter-related bloodstream infections (CRBSI). It is not intended for treatment of existing infection. The device is a short-term use catheter.	The activity of the antimicrobial agents minocycline, rifampin and chlorhexidine is located at the internal and external catheter surfaces, and is not intended for treatment of existing infections. This combination of antimicrobials has been shown to reduce microbial colonization of the catheter. The effectiveness was evaluated using in vitro methods; no correlation between in vitro and clinical outcome has currently been ascertained. Controlled studies of this product have not been conducted in pregnant women, pediatric or neonatal patients. The benefits of the use of this catheter should be weighed against any possible risk. Consider CDC Guidelines and institutional protocols for catheter exchange.
Prescription Only or Over the Counter	Prescription Only	Prescription Only

7. Comparison to Predicate Device and Substantial Equivalence:

The table below includes a comparison of the technological characteristics between the predicate device and subject device.

	PREDICATE DEVICE	**SUBJECT DEVICE**	**COMMENT**
	Cook® Spectrum®/Spectrum® Glide Central Venous Catheters (K081113)	**Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)**	
Regulation	21 CFR 880.5200	21 CFR 880.5200	Same
Product Code	FOZ	FOZ	Same
Classification	II	II	Same

	PREDICATE DEVICE	SUBJECT DEVICE	COMMENT
	Cook® Spectrum®/Spectrum® Glide Central Venous Catheters (K081113)	**Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)**	
Indications for Use (General Use)	The Cook® Spectrum®/ Spectrum® Glide Central Venous Catheter is used for: • Continuous or intermittent drug infusions • Central venous blood pressure monitoring (CVP) • Acute hyperalimentation • Blood sampling • Delivery of whole blood or blood products • Power injection of contrast media	The Cook® Spectrum® 2 MRC Central Venous Catheter is indicated to provide short-term (<30 days) central venous access intended for: • Continuous or intermittent drug infusion • Central venous blood pressure monitoring (CVP) • Acute hyperalimentation • Blood sampling • Delivery of whole blood or blood products • Simultaneous, separate infusion of drugs and • Power injection of contrast media (max 300 psi).	Different /See comment 1
Indications for Use (Antimicrobial Activity)	The activity of the antimicrobial agents, minocycline and rifampin, is localized at the internal and external catheter surface and helps to provide protection against catheter-related bloodstream infections (CRBSI). It is not intended for treatment of existing infection. The device is a short-term use catheter.	The activity of the antimicrobial agents, minocycline, rifampin and chlorhexidine is located at the internal and external catheter surfaces and is not intended for treatment of existing infections. This combination of antimicrobials has been shown to reduce microbial colonization of the catheter. The effectiveness was evaluated using in vitro methods; no correlation between in vitro and clinical outcome has currently been ascertained.	Different /See comment 1
Special Patient Populations	Patient age / weight recommendation is not specified The device is a short-term use catheter.	IFU indicates controlled studies of this product have not been conducted in pregnant women, pediatric or neonatal patients and that the benefits of the use of this catheter should be weighed against any possible risk. Consider CDC Guidelines and institutional protocols for catheter exchange.	Different /See comment 1
Contraindications	IFU contraindicates use in patients with known allergy or history of allergy to tetracyclines (including minocycline) or rifampin.	Identical to predicate	Same
Chlorhexidine Hypersensitivity Potential	N/A	IFU includes a warning for the potential development of a hypersensitivity reaction.	Different /See comment 1

	PREDICATE DEVICE	SUBJECT DEVICE	COMMENT
	Cook® Spectrum®/Spectrum® Glide Central Venous Catheters (K081113)	**Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)**	
Flow Rate	The flow rate of the Cook Central Venous Catheters may not exceed 10 mL/sec.	The flow rate may not exceed 10 mL/sec for the main lumen and 5 mL/sec for the two smaller lumens.	Different /See comment 2
Maximum Pressure Limit for Power Injection	325 psi	300 psi	Different /See comment 2
Concentration of Antimicrobials on Catheter Shaft (µg/cm)	7 Fr: Minocycline: 520 Rifampin: 470	Minocycline: 450 Rifampin: 450 Chlorhexidine: 350	Different /See comment 2
Device for One-time Use	Yes	Identical to predicate	Same
Catheter Placement Method	Percutaneous via Seldinger technique	Identical to predicate	Same
Catheter Tip Target Anatomy	SVC-RA junction	Identical to predicate	Same
Catheter Tip Location Confirmation Method	ECG/Ultrasound/ Fluoroscopy	Identical to predicate	Same
Hydrophilic Coating	With or without hydrophilic coating	No hydrophilic coating	Different /See comment 2
Catheter Lumen Design	Round, Crescent	Round	Different /See comment 2
Catheter Shaft Markings	Yes	Identical to predicate	Same
Catheter Tip	Molded tip	Bonded tip	Different /See comment 2
Catheter Shaft Material	Polyurethane (aromatic polyester)	Polyurethane (aliphatic polyether)	Different /See comment 2
Number of Catheter Lumens	Two, three, or five	Three	Same as 7 Fr predicate
Catheter Shaft Outer Diameter	7 to 10 Fr	7 Fr	Same as 7 Fr predicate
Catheter Shaft Length	15 to 25 cm	Identical to predicate	Same
Extension Tube Length	Distal: 5.5 +/- 1 cm Medial: 10.0 +/- 1 cm Proximal: 6.5 +/- 1 cm	Distal: 7.8 +/- 0.2 cm Medial: 12.9 +/- 0.8 cm Proximal: 10.3 +/- 0.8 cm	Different /See comment 2
Extension Tube Diameter	ID (inches): 0.80-0.120 OD (inches): 0.083-0.123	ID (inches): 0.058-0.088 OD (inches): 0.061-0.091	Different /See comment 2
Main Accessory Components	Wire Guide, dilator, introducer needle, syringe, and injection caps	Identical to predicate	Same

	PREDICATE DEVICE	SUBJECT DEVICE	COMMENT
	Cook® Spectrum®/Spectrum® Glide Central Venous Catheters (K081113)	**Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)**	
Wire Guide	Included	Included as part of the standard set or in a kit tray. None for stand-alone catheter.	Same for kit tray
Packaging	Kit tray with Tyvek® lid stock	Two configurations available: 1) Kit tray with Tyvek® lid stock 2) CVC catheter (in a foil pouch) packaged inside a Tyvek outer pouch	Different /See comment 2
Sterilization Method	EO	For packaging configurations described above: 1) E-beam of foil pouch, then EO of entire tray 2) E-beam of foil pouch, then EO of foil pouch in Tyvek pouch	Different /See comment 2
Sterility Assurance Level	10^{-6}	Identical to predicate	Same

Discussions of differences in technological characteristics

Comment 1

Added specificity to labeling regarding general use, the reduction of microbial colonization established through in vitro methods, special patient populations, indwell times/catheter exchanges, and chlorhexidine hypersensitivity potential. Reduction of microbial colonization of the catheter was demonstrated through microbiological testing using an In Vitro Microbial Colonization Model and clinically virulent microorganisms.

Comment 2

Technological design modifications are intended to increase flexibility and improve usability. The following tests were performed to demonstrate substantial equivalence: tensile strength, flow rate, power injection, static burst, liquid leakage, air leakage, kink (flow), MRI safety. radiopacity, luer hub compatibility, bending fatigue, insertability, chemical injectate compatibility, extension tube clamp functionality, dimensional testing, and sterilization. The difference between the proposed device and the predicate does not raise different questions of safety and effectiveness and that the device is as safe and effective as a legally marketed device.

8. Technological Characteristics and Performance Testing:

The single use, sterile Cook® Spectrum® 2 MRC Central Venous Catheter described in this summary was tested and demonstrated to be in conformance with the following FDA-recognized standards:

- BS EN ISO 10555-1: 2013: Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements
- BS EN ISO 10555-3: Intravascular catheters - Sterile and single-use catheters - Part 3: Central venous catheters
- BS EN 13868: Catheters - Test Methods for Kinking of Single Lumen Catheters and Medical Tubing
- ASTM F2503-13: Standard Practice For Marking Medical Devices And Other Items For Safety In The Magnetic Resonance Environment
- ASTM F640: Standard Test Methods for Determining Radiopacity for Medical Use
- BS EN ISO 80369-7:2017: Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications

<u>Biocompatibility</u>

According to the requirements identified in ISO 10993-1 for externally communicating devices with circulating blood contact for up to a 30-day duration, the following biocompatibility endpoints were evaluated and adequately addressed:

- *Cytotoxicity,*
- *Sensitization,*
- *Irritation,*
- *Hemolysis,*
- *Complement Activation,*
- *Hemocompatibility,*
- *Materials Mediated Pyrogenicity,*
- *Implantation (4-week),*
- *Chronic Toxicity*
- *Carcinogenicity,*
- *Genotoxicity*

Particulate matter testing was conducted in accordance with USP<788> Particulate Matter in Injection and met the USP acceptance criteria.

Microbiological evaluations

The Cook® Spectrum® 2 MRC Central Venous Catheter has been studied in an In Vitro Microbial Colonization Model that simulated elution of antimicrobial agents over intravascular dwell times up to 4 weeks. Results from the microbiological performance testing including lack of development of antimicrobial resistance, and comparison of log reductions in colonizing microbe concentrations, demonstrated that the microbiological performance of the Cook® Spectrum® 2 MRC Central Venous Catheter is substantially equivalent to the predicate and reference devices.

Sterility, Shipping and Shelf life

- Terminal sterilization is accomplished by electron-beam processing of the subject catheter within a sealed (inner) foil pouch. Secondary EO sterilization is used to sterilize the outside of the foil pouch and the airspace within the tray or (outer) Tyvek® pouch. Applicable standards include:
    - Terminal sterilization: Method 1 BS EN ISO 11137-1:2015+A2:2019
    - Secondary EO sterilization: Half-cycle method ANSI/AAMI/ISO 11135-1
    - EO residuals: ISO 10993-7:2008/(R)2012

- Package integrity testing, after environmental conditioning and simulated transportation in accordance with ISTA 3A, was conducted on the final, packaged, and sterile devices.

- Sterile Barrier Packaging Testing was performed on the proposed device according to these standards:
    - Seal strength ASTM F88/F88-15
    - Dye penetration ASTM F1929-15

- Shelf life of 6 months was validated using the FDA-recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

9. Conclusions:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Cook® Spectrum® 2 MRC Central Venous Catheter is substantially equivalent to the Cook® Spectrum®/Spectrum® Glide Central Venous Catheter with respect to the indications for use, target populations, treatment method, and technological characteristics.