November 27, 2024

Spectrum Vascular
Sharon Klugewicz
Chief Operating Officer
50 Main Street
Suite 1000
White Plains, New York 10606

Re: K241115
Trade/Device Name: SV Spectrum MRC Central Venous Catheter; SV Spectrum MR Central Venous Catheter; SV Central Venous Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: October 28, 2024
Received: October 29, 2024

Dear Sharon Klugewicz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241115

Device Name
SV Spectrum MRC Central Venous Catheter
SV Spectrum MR Central Venous Catheter
SV Central Venous Catheter

Indications for Use *(Describe)*
The SV Spectrum 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
• 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.

The SV Spectrum MR 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 and rifampin is localized at the internal and external catheter surfaces 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 SV 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).

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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Spectrum Vascular: SV Spectrum MRC Central Venous Catheter
K241115 - 510(k) Summary

1. SUBMITTER INFORMATION

Applicant:	Spectrum Vascular
Contact:	Sharon Klugewicz
Phone:	516-425-4446
Email:	sklugewicz@spectrumvascular.com
Address	50 Main Street, Suite 1000 White Plains, NY 10606

2. CORRESPONDENT INFORMATION

Contact:	Sharon Klugewicz
Title:	Chief Operating Officer / SVP Regulatory Affairs
Firm:	Spectrum Vascular

3. DATE PREPARED: NOVEMBER 27, 2024

4. DEVICE INFORMATION

Device Name:	SV Spectrum MRC Central Venous Catheter SV Spectrum MR Central Venous Catheter SV Central Venous Catheter
Common Name:	Catheter, Intravascular
Regulation Number:	880.5200
Regulation Name:	Intravascular Catheter
Product Code:	FOZ
Regulatory Class:	Class II

5. PREDICATE DEVICE INFORMATION

Device Name:	Cook® Spectrum® 2 MRC Central Venous Catheter
Common Name:	Catheter, Intravascular
510(k) Number:	K223648
Manufacturer:	Cook Medical

The predicate device has not been subject to a design related recall.

6. DEVICE DESCRIPTION

The SV Spectrum MRC Central Venous Catheter (CVC) 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 SV Spectrum 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 SV Spectrum 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 SV Spectrum MRC CVC has demonstrated efficacy against the following organisms:

- Staphylococcus aureus
- Staphylococcus epidermidis
- Enterococcus faecalis
- Escherichia coli
- Klebsiella pneumoniae
- Acinetobacter baumanni
- Candida albicans
- Candida glabrata

The effectiveness was evaluated using in vitro methods. 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 SV Spectrum 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.

The SV Spectrum MR Central Venous Catheter is identical to the SV Spectrum MRC Central Venous Catheter except that it is not coated with chlorohexidine antiseptic.

The SV Central Venous Catheter is identical to the SV Spectrum MRC Central Venous Catheter and SV Spectrum MR Central Venous Catheter except it is not impregnated with minocycline or rifampin, nor is it coated with chlorhexidine antiseptic.

7. INDICATIONS FOR USE

The SV Spectrum 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
- 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.

The SV Spectrum MR 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 and rifampin is localized at the internal and external catheter surfaces 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 SV 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).

8. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Predicate Device	**Subject Device**		
	Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)	**SV Spectrum MRC Central Venous Catheter**	**SV Spectrum MR Central Venous Catheter (previously cleared under K033843)**	**SV Central Venous Catheter (previously cleared under K081113)**
Regulation	21 CFR 880.5200	21 CFR 880.5200	21 CFR 880.5200	21 CFR 880.5200
Product Code	FOZ	FOZ	FOZ	FOZ
Classification	II	II	II	II
Indications for Use (General Use)	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	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	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	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

	Predicate Device	**Subject Device**		
	Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)	**SV Spectrum MRC Central Venous Catheter**	**SV Spectrum MR Central Venous Catheter (previously cleared under K033843)**	**SV Central Venous Catheter (previously cleared under K081113)**
	• Simultaneous, separate infusion of drugs and • Power injection of contrast media (max 300 psi).	• Delivery of whole blood or blood products • Simultaneous, separate infusion of drugs • Power injection of contrast media (max 300 psi).	• Delivery of whole blood or blood products • Simultaneous, separate infusion of drugs and • Power injection of contrast media (max 300 psi).	• Delivery of whole blood or blood products • Simultaneous, separate infusion of drugs and • Power injection of contrast media (max 300 psi).
Indications for Use (Antimicrobial Activity)	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.	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	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	Not applicable

	Predicate Device	Subject Device		
	Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)	**SV Spectrum MRC Central Venous Catheter**	**SV Spectrum MR Central Venous Catheter (previously cleared under K033843)**	**SV Central Venous Catheter (previously cleared under K081113)**
		been ascertained. The benefits of the use of this catheter should be weighed against any possible risk. Consider CDC Guidelines and institutional protocols for catheter exchange.		
Special Patient Populations	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.	IFU indicates controlled studies of this product have not been conducted in pregnant women, pediatric or neonatal patients due to teratogenicity of minocycline and rifampin at systemic doses 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.	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.	Not applicable
Contraindications	Patients with allergy or hypersensitivity to tetracyclines (including minocycline), rifampin	Allergy, history of allergy, or hypersensitivity to tetracyclines	Patients with allergy or hypersensitivity to tetracyclines (including	

	or chlorohexidine.	(including		

	Predicate Device	**Subject Device**		
	Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)	**SV Spectrum MRC Central Venous Catheter**	**SV Spectrum MR Central Venous Catheter (previously cleared under K033843)**	**SV Central Venous Catheter (previously cleared under K081113)**
	Those who are pregnant (due to teratogenicity of minocycline and rifampin at systemic doses). Pediatrics.	minocycline), rifampin or chlorohexidine. Those who are pregnant (due to teratogenicity of minocycline and rifampin at systemic doses). Pediatrics.	minocycline or rifampin). Those who are pregnant (due to teratogenicity of minocycline and rifampin at systemic doses).	Pediatrics.
Flow Rate	The flow rate may not exceed 10 mL/sec for the main lumen and 5 mL/sec for the two smaller lumens.	The flow rate may not exceed 10 mL/sec for the main lumen and 5 mL/sec for the two smaller lumens.	The flow rate may not exceed 10 mL/sec for the main lumen and 5 mL/sec for the two smaller lumens.	The flow rate may not exceed 10 mL/sec for the main lumen and 5 mL/sec for the two smaller lumens.
Maximum Pressure Limit for Power Injection	300 psi	300 psi	300 psi	300 psi
Concentration of Antimicrobials on Catheter Shaft (µg/cm)	Minocycline: 450 Rifampin: 450 Chlorhexidine: 350	Minocycline: 450 Rifampin: 450 Chlorhexidine: 350	Minocycline: 450 Rifampin: 450 Not applicable for chlorhexidine.	Not applicable
Device for One-time Use	Yes	Yes	Yes	Yes

Spectrum Vascular: SV Spectrum MRC Central Venous Catheter
K241115 - 510(k) Summary

	Predicate Device	**Subject Device**		
	Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)	**SV Spectrum MRC Central Venous Catheter**	**SV Spectrum MR Central Venous Catheter (previously cleared under K033843)**	**SV Central Venous Catheter (previously cleared under K081113)**
Catheter Placement Method	Percutaneous via Seldinger technique	Percutaneous via Seldinger technique	Percutaneous via Seldinger technique	Percutaneous via Seldinger technique
Catheter Tip Target Anatomy	SVC-RA junction	SVC-RA junction	SVC-RA junction	SVC-RA junction
Catheter Tip Location Confirmation Method	ECG/Ultrasound/ Fluoroscopy	ECG/Ultrasound/ Fluoroscopy	ECG/Ultrasound/ Fluoroscopy	ECG/Ultrasound/ Fluoroscopy
Hydrophilic Coating	No hydrophilic coating	No hydrophilic coating	No hydrophilic coating	No hydrophilic coating
Catheter Lumen Design	Round	Round	Round	Round
Catheter Shaft Markings	Yes	Yes	Yes	Yes
Catheter Tip	Bonded tip	Bonded tip	Bonded tip	Bonded tip
Catheter Shaft Material	Polyurethane (aliphatic polyether)	Polyurethane (aliphatic polyether)	Polyurethane (aliphatic polyether)	Polyurethane (aliphatic polyether)
Number of Catheter Lumens	Three	Three	Three	Three
Catheter Shaft Outer Diameter	7 Fr	7 Fr	7 Fr	7 Fr

Spectrum Vascular: SV Spectrum MRC Central Venous Catheter
K241115 - 510(k) Summary

	Predicate Device	**Subject Device**		
	Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)	**SV Spectrum MRC Central Venous Catheter**	**SV Spectrum MR Central Venous Catheter (previously cleared under K033843)**	**SV Central Venous Catheter (previously cleared under K081113)**
Catheter Shaft Length	15 to 25 cm	15 to 25 cm	15 to 25 cm	15 to 25 cm
Extension Tube Length	Distal: 7.8 +/- 0.2 cm Medial: 12.9 +/- 0.8 cm Proximal: 10.3 +/- 0.8 cm	Distal: 7.8 +/- 0.2 cm Medial: 12.9 +/- 0.8 cm Proximal: 10.3 +/- 0.8 cm	Distal: 7.8 +/- 0.2 cm Medial: 12.9 +/- 0.8 cm Proximal: 10.3 +/- 0.8 cm	Distal: 7.8 +/- 0.2 cm Medial: 12.9 +/- 0.8 cm Proximal: 10.3 +/- 0.8 cm
Extension Tube Diameter	ID (inches): 0.058-0.088 OD (inches): 0.061-0.091	ID (inches): 0.058-0.088 OD (inches): 0.061-0.091	ID (inches): 0.058-0.088 OD (inches): 0.061-0.091	ID (inches): 0.058-0.088 OD (inches): 0.061-0.091
Main Accessory Components	Wire Guide, dilator, introducer needle, syringe, and injection caps	Wire Guide, dilator, introducer needle, syringe, and injection caps	Wire Guide, dilator, introducer needle, syringe, and injection caps	Wire Guide, dilator, introducer needle, syringe, and injection caps
Wire Guide	Included as part of the standard set or in a kit tray. None for stand-alone catheter.	Included as part of the standard set or in a kit tray. None for stand-alone catheter.	Included as part of the standard set or in a kit tray. None for stand-alone catheter.	Included as part of the standard set or in a kit tray. None for stand-alone catheter.
Packaging	Two configurations available: • Kit tray with Tyvek lid stock • CVC catheter (in a foil pouch) inside a Tyvek outer pouch	• Kit tray with Tyvek lid stock • CVC catheter (in a foil pouch) inside a Tyvek outer pouch	• Kit tray with Tyvek lid stock • CVC catheter (in a foil pouch) inside a Tyvek outer pouch	Kit tray with Tyvek lid stock

Spectrum Vascular: SV Spectrum MRC Central Venous Catheter
K241115 - 510(k) Summary

	Predicate Device	Subject Device		
	Cook® Spectrum® 2 MRC Central Venous Catheter (K223648)	**SV Spectrum MRC Central Venous Catheter**	**SV Spectrum MR Central Venous Catheter (previously cleared under K033843)**	**SV Central Venous Catheter (previously cleared under K081113)**
Sterilization Method	For packaging configurations described above: • E-beam of foil pouch, then EO of entire tray • E-beam of foil pouch, then EO of foil pouch in Tyvek pouch	For packaging configurations described above: • E-beam of foil pouch, then EO of entire tray • E-beam of foil pouch, then EO of foil pouch in Tyvek pouch	For packaging configurations described above: • E-beam of foil pouch, then EO of entire tray • E-beam of foil pouch, then EO of foil pouch in Tyvek pouch	Ethylene Oxide (EO)
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	10^{-6}
Shelf-life	6 months	3 years	3 years	3 years

Summary:

The SV Spectrum MRC Central Venous Catheter (MRC) that is the subject of this 510(k) is identical to the predicate Cook Spectrum 2 MRC Central Venous Catheter (K223648) in design and all device attributes, with the exception of extending the shelf life from the previously cleared 6-month shelf life to a 3-year shelf life. Testing is provided to support and demonstrate the performance of the SV Spectrum MRC Central Venous Catheter after 3 years of aging. The aged device met all acceptance criteria for device performance and thus, is Substantially Equivalent to the predicate device.

Spectrum Vascular also intends to market a version of the SV Spectrum MR catheter without the chlorhexidine coating, the SV Spectrum MR Central Venous Catheter, and an uncoated version without any drug impregnated or coating the device, the SV Central Venous Catheter. The only variation between the three versions listed are the impregnation of Minocycline and Rifampin on the MRC and MR versions, and the addition of a Chlorhexidine coating specific to the MRC version of the device. Testing on 3-year aged samples demonstrates performance to support clearance of all three devices with a 3-year shelf life.

The Cook Spectrum MR CVC, which is representative of the SV Spectrum MR CVC in terms of antimicrobial efficacy (only the name will change on the labeling), has an established 3-year shelf-life based on results from the 3-year real-time aged antimicrobial efficacy testing originally provided in K033843. The currently marketed MR CVC, and CVC (K081113), have been commercially available on

the market with a 36-month shelf life for over 15 years and have not changed functionally. Additionally, the Cook Spectrum MR CVC has been clinically validated in large scale studies, with no new concerns of safety and effectiveness.

Performance testing is provided below in Section 9.

9. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

The medical device in its final finished form is identical to the Cook® Spectrum® 2 MRC Central Venous Catheter in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Electrical Safety

Not applicable. The device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Electromagnetic Compatibility (EMC)

Not applicable. The device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software

Not applicable. The device contains no software.

Performance Testing

Performance testing to the following standards was conducted:

- BS EN ISO 10555-1:2013 + A1:2017, Intravascular catheters – Sterile and single-use catheters. Part 1: General requirements
- BS EN ISO 10555-3:2013, Intravascular catheters — Sterile and single-use catheters Part 3: Central venous catheters
- ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F2503-20, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Shelf-Life Testing (aged product up to 36 months):

- Package Integrity
- Simulated Transport Testing
- Bubble Leak, Seal Strength and Visual Inspection
- Mechanical Performance Testing of the Catheter: Tensile, Power Injection and Static Burst, Liquid & Air Leakage, Bending Fatigue, Suture Retention Strength, Extension Tube Clamp Functionality, Shaft Diameter and Length
- Drug Stability (Drug Content, Degradant and In vitro Diffusion, and Particulate Matter Testing)
- Anti-Microbial Function (Durability to assess antimicrobial effectiveness of gram positive, gram negative, and fungal organisms).

10. CONCLUSION

The results of the performance testing described above demonstrate that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.