8/10/2026

Spectrum Vascular
Sharon Klugewicz
Sr VP, Quality & Regulatory Affairs
50 Main St.
Suite 1000
White Plains, New York 10606

Re: K260165
Trade/Device Name: Unimpregnated Central Venous Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: July 9, 2026
Received: July 9, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

GANG PENG -S

Gang Peng for
David Wolloscheck
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260165

Please provide the device trade name(s).

Unimpregnated Central Venous Catheter

Please provide your Indications for Use below.

The Unimpregnated Central Venous Catheter (Non-Power Injectable) is used for:
1. Continuous or intermittent drug infusions
2. Central venous blood pressure monitoring (CVP)
3. Acute hyperalimentation
4. Blood sampling
5. Delivery of whole blood or blood products
6. Simultaneous, separate infusion of drugs for multi-lumen catheters only

The device is a short-term use catheter, intended for less than 30 days.
The Cook dilator is used for dilating puncture sites or catheter tracts.
The Unimpregnated Central Venous Catheter (Non-Power Injectable) is intended for adult and pediatric populations.

The Unimpregnated Central Venous Catheter with Power Injection is used for:
1. Continuous or intermittent drug infusions
2. Central venous blood pressure monitoring (CVP)
3. Acute hyperalimentation
4. Blood sampling
5. Delivery of whole blood or blood products
6. Simultaneous, separate infusion of drugs for multi-lumen catheters only
7. Power injection of contrast media*

*The flow rate may not exceed 3 mL/sec for 4.0 and 5.0 French catheters and 10 mL/sec for 7.0, 8.0, 9.0 and 10.0 French catheters. Verify prior to use that the maximum safety cut-off pressure limit is set at or below 250 psi for 4.0 and 5.0 French catheters and 325 psi for 7.0, 8.0, 9.0 and 10.0 French catheters.
The device is a short-term use catheter, intended for less than 30 days.
The 9.0 and 10.0 French catheters include an inner catheter to facilitate insertion of the main catheter.
The Cook dilator is used for dilating puncture sites or catheter tracts.
The Unimpregnated Central Venous Catheter with power injection is intended for adult and pediatric populations.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

1. SUBMITTER INFORMATION

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

2. CORRESPONDENT INFORMATION

Contact:	Ms. Sharon Klugewicz
Title:	SVP, Quality and Regulatory Affairs
Firm:	Spectrum Vascular 50 Main Street, Suite 1000 White Plains, NY 10606
Phone:	516-425-4446
Email:	sklugewicz@spectrumvascular.com

3. DATE PREPARED: AUGUST 6, 2026

4. DEVICE INFORMATION

Device Name:	Unimpregnated Central Venous Catheter
Common Name:	Intravascular catheter
Regulation Number:	21 CFR 880.5200
Regulation Name:	Intravascular catheter
Product Code:	FOZ
Regulatory Class:	Class II

5. PREDICATE DEVICE INFORMATION

Predicate Device Name:	Cook Unimpregnated Central Venous Catheter
510(k) Number:	K182252
Manufacturer:	Cook Incorporated

6. DEVICE DESCRIPTION

The Unimpregnated Central Venous Catheter set includes a central venous catheter (CVC), wire guide, access needle, and syringe. The CVC is inserted into the vasculature using the Seldinger technique. The tip of the catheter is then advanced until it is above the superior vena cava-right atrium (SVC-RA) junction. The CVC is a single, double, triple, or five-lumen shaft manufactured from polyethylene, ethylene-vinyl acetate, or polyurethane tubing. The CVC is offered with and without power injection, and supplied in multiple size configurations, ranging from 2.5 to 10 French, to support a variety of vascular access needs. Single lumen CVCs are designed with a pre-molded winged hub on the proximal end. Double, triple, and five lumen CVCs are manufactured with a manifold assembly, which is designed as a winged manifold connected to extension tubes. Each extension tube has a slide clamp and is manufactured with a proximal winged hub. The wire guide is manufactured with stainless steel and may be coated with polytetrafluoroethylene (PTFE). The access needle is manufactured from stainless steel. Additional set configurations may also contain a dilator, injection caps, clamps, catheter securement device, connecting tube, and other convenience accessories.

7. INDICATIONS FOR USE

The Unimpregnated Central Venous Catheter (Non-Power Injectable) is used for:

1. Continuous or intermittent drug infusions
2. Central venous blood pressure monitoring (CVP)
3. Acute hyperalimentation
4. Blood sampling
5. Delivery of whole blood or blood products
6. Simultaneous, separate infusion of drugs for multi-lumen catheters only

The device is a short-term use catheter, intended for less than 30 days.

The Cook dilator is used for dilating puncture sites or catheter tracts.

The Unimpregnated Central Venous Catheter (Non-Power Injectable) is intended for adult and pediatric populations.

The Unimpregnated Central Venous Catheter with Power Injection is used for:

1. Continuous or intermittent drug infusions
2. Central venous blood pressure monitoring (CVP)
3. Acute hyperalimentation
4. Blood sampling
5. Delivery of whole blood or blood products
6. Simultaneous, separate infusion of drugs for multi-lumen catheters only

7. Power injection of contrast media*

   *The flow rate may not exceed 3 mL/sec for 4.0 and 5.0 French catheters and 10 mL/sec for 7.0, 8.0, 9.0 and 10.0 French catheters. Verify prior to use that the maximum safety cut-off pressure limit is set at or below 250 psi for 4.0 and 5.0 French catheters and 325 psi for 7.0, 8.0, 9.0 and 10.0 French catheters.

The device is a short-term use catheter, intended for less than 30 days.

The 9.0 and 10.0 French catheters include an inner catheter to facilitate insertion of the main catheter.

The Cook dilator is used for dilating puncture sites or catheter tracts.

The Unimpregnated Central Venous Catheter with power injection is intended for adult and pediatric populations.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Other than the change in ink as noted in Table 1, the subject device is identical to the predicate device.

Table 1: Technological Comparison to Predicate Device

	Predicate Device (K182252)	**Subject Device (K260165)**	**Comparison**
Regulation	21 CFR 880.5200	21 CFR 880.5200	Same
Product Code	FOZ	FOZ	Same
Classification	Class II	Class II	Same
Indications for Use	The Cook Unimpregnated Central Venous Catheter (Non-Power Injectable) is used for: 1. Continuous or intermittent drug infusions 2. Central venous blood pressure monitoring (CVP) 3. Acute hyperalimentation 4. Blood sampling 5. Delivery of whole blood or blood products 6. Simultaneous, separate infusion of drugs for multi-lumen catheters only. The device is a short-term use catheter, intended for less than 30 days. The Cook dilator is used for dilating puncture sites or catheter tracts.	The Unimpregnated Central Venous Catheter (Non-Power Injectable) is used for: 1. Continuous or intermittent drug infusions 2. Central venous blood pressure monitoring (CVP) 3. Acute hyperalimentation 4. Blood sampling 5. Delivery of whole blood or blood products 6. Simultaneous, separate infusion of drugs for multi-lumen catheters only The device is a short-term use catheter, intended for less than 30 days. The Cook dilator is used for dilating puncture sites or catheter tracts.	The subject device Indications for Use is the same as the predicate device with the exception of the “Cook” name being removed in the device name.

	Predicate Device (K182252)	**Subject Device (K260165)**	**Comparison**
	The Cook Unimpregnated Central Venous Catheter (Non-Power Injectable) is intended for adult and pediatric populations. The Cook Unimpregnated Central Venous Catheter with power injection is used for: 1. Continuous or intermittent drug infusions 2. Central venous blood pressure monitoring (CVP) 3. Acute hyperalimentation 4. Blood sampling 5. Delivery of whole blood or blood products 6. Simultaneous, separate infusion of drugs for multi-lumen catheters only 7. Power injection of contrast media* *The flow rate may not exceed 3 mL/sec for 4.0 and 5.0 French catheters and 10 mL/sec for 7.0, 8.0, 9.0, and 10.0 French catheters. Verify prior to use that the maximum safety cut-off pressure limit is set at or below 250 psi for 4.0 and 5.0 French catheters and 325 psi for 7.0, 8.0, 9.0, and 10.0 French catheters. The device is a short-term use catheter, intended for less than 30 days. The 9.0 and 10.0 French catheters include an inner catheter to facilitate insertion of the main catheter. The Cook dilator is used for dilating puncture sites or catheter tracts. The Cook Unimpregnated Central Venous Catheter with power injection is intended for adult and pediatric populations.	The Unimpregnated Central Venous Catheter (Non-Power Injectable) is intended for adult and pediatric populations. The Unimpregnated Central Venous Catheter with Power Injection is used for: 1. Continuous or intermittent drug infusions 2. Central venous blood pressure monitoring (CVP) 3. Acute hyperalimentation 4. Blood sampling 5. Delivery of whole blood or blood products 6. Simultaneous, separate infusion of drugs for multi-lumen catheters only 7. Power injection of contrast media* *The flow rate may not exceed 3 mL/sec for 4.0 and 5.0 French catheters and 10 mL/sec for 7.0, 8.0, 9.0 and 10.0 French catheters. Verify prior to use that the maximum safety cut-off pressure limit is set at or below 250 psi for 4.0 and 5.0 French catheters and 325 psi for 7.0, 8.0, 9.0 and 10.0 French catheters. The device is a short-term use catheter, intended for less than 30 days. The 9.0 and 10.0 French catheters include an inner catheter to facilitate insertion of the main catheter. The Cook dilator is used for dilating puncture sites or catheter tracts. The Unimpregnated Central Venous Catheter with power injection is intended for adult and pediatric populations.	
Patient Population	Neonates/Newborns; Infants; Children; Adolescents; Adults	Neonates/Newborns; Infants; Children; Adolescents; Adults	Same
Catheter Placement Method	Percutaneously via Seldinger technique	Percutaneously via Seldinger technique	Same
Catheter Tip Target Anatomy	SVC-RA junction	SVC-RA junction	Same

	Predicate Device (K182252)	**Subject Device (K260165)**	**Comparison**
Catheter tip Location Confirmation Method	ECG/Ultrasound/Fluoroscopy	ECG/Ultrasound/Fluoroscopy	Same
Power Injectable Catheter Configurations (7-10Fr)	Dual Lumen: 8 Fr Triple Lumen: 7, 9 Fr Five-Lumen: 10 Fr	Dual Lumen: 8 Fr Triple Lumen: 7, 9 Fr Five-Lumen: 10 Fr	Same
Upper Pressure Limit for Power Injection (7-10Fr)	325 psi	325 psi	Same
Power Injectable Catheter Configurations (4-5 Fr)	Dual Lumen: 4, 5 Fr Triple Lumen: 5 Fr	Dual Lumen: 4, 5 Fr Triple Lumen: 5 Fr	Same
Upper Pressure Limit for Power Injection (4-5 Fr)	250 psi	250 psi	Same
Catheter Shaft Material	Polyethylene Ethylene-Vinyl Acetate Polyurethane	Polyethylene Ethylene-Vinyl Acetate Polyurethane	Same
Catheter Shaft Marking Ink	*UVA Ink (Color #1 Black)*	*UVA Ink (TPC 980 Black Ink)*	Different: Biocompatibility testing was conducted in accordance with ISO 10993 and supports a determination that the new ink is biocompatible and thus the catheters are substantially equivalent. An additional ink legibility performance test was conducted to demonstrate that the device meets its design requirements and performs as intended.
Catheter Hub Material	Polyethylene Polyurethane	Polyethylene Polyurethane	Same
Number of Catheter Lumens	1, 2, 3, 5	1, 2, 3, 5	Same
Catheter Outer Diameter (Fr)	Single – 2.5, 3, 4, 5, 6, 6.3 Fr Dual – 4, 5, 7.5, 8 Fr Triple – 5, 7, 9 Fr Five – 10 Fr	Single – 2.5, 3, 4, 5, 6, 6.3 Fr Dual – 4, 5, 7.5, 8 Fr Triple – 5, 7, 9 Fr Five – 10 Fr	Same
Catheter Length	5 to 26.5 cm	5 to 26.5 cm	Same
Packaging	PETG Tray w/ Tyvek Lidstock	PETG Tray w/ Tyvek Lidstock	Same
Single Use?	Yes	Yes	Same
Sterilization Method	EtO	EtO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same

9. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

The catheter of the subject device is identical to the Unimpregnated Central Venous Catheter cleared in K182252 with the exclusion of the marker ink. Additional biocompatibility testing on the subject device was conducted in accordance with the ISO 10993 series.

Electrical Safety

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

Electromagnetic Compatibility (EMC)

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

Software

Not applicable. The subject device contains no software.

Performance Testing

An additional ink legibility performance test was conducted to demonstrate that the device meets its design requirements and performs as intended.

10. CONCLUSION

The results of the performance testing described above demonstrate that the Unimpregnated Central Venous Catheter performs equivalently as compared to the predicate device and supports a determination of substantial equivalence.