May 17, 2019

Cook Incorporated
Chelsea Woods
Regulatory Affairs Specialist
750 Daniels Way
P.Box 489
Bloomington, Indiana 47404

Re: K182252
Trade/Device Name: Cook Unimpregnated Central Venous Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ, DRE
Dated: April 15, 2019
Received: April 16, 2019

Dear Chelsea Woods:

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/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,

for Tina Kiang, Ph.D
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)*
K182252

Device Name
Cook Unimpregnated Central Venous Catheter

Indications for Use *(Describe)*
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 Cook Unimpregnated Central Venous Catheter (Non-Power Injectable) is intended for adult and pediatric populations.

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."

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)*
K182252

Device Name
Cook Unimpregnated Central Venous Catheter

Indications for Use *(Describe)*
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.

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)

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510(k) SUMMARY

K182252
Cook Unimpregnated Central Venous Catheter
21 CFR §807.92
Date Prepared: May 16, 2019

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Primary Contact:	Chelsea Woods
Secondary Contact:	Ram Iyer, Ph.D. RAC
Email:	regsubmissions@cookmedical.com
Contact Phone Number:	(812) 335-3575 x104707
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	**Cook Unimpregnated Central Venous Catheter**
Common Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Classification Name:	Intravascular catheter
Regulation:	21 CFR §880.5200
Product Code:	FOZ; DRE
Device Class:	II
Classification Panel:	General Hospital

Predicate Device:

The Cook Unimpregnated Central Venous Catheter is substantially equivalent to the following devices:

- Cook Central Venous Catheters with or without Heparin (K081113, Cook Incorporated) cleared on July 30, 2008

Device Description:

The Cook Unimpregnated Central Venous Catheter is a single use sterile intravascular catheter designed to be inserted into a patient's vascular system. 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 configurations include a single, dual, triple, or five-lumen shaft manufactured from polyethylene, ethylene-vinyl acetate, or polyurethane tubing. The CVC is manufactured with an outside diameter between 2.5 and 10 French and has a length between 5 and 40 centimeters dependent on the configuration. Single lumen CVCs are designed with a pre-molded winged hub on the proximal end. Dual, triple, and five-lumen CVCs are designed with a manifold assembly, which is comprised of a winged manifold connected to extension tubes. Each extension tube has a slide clamp and is manufactured with a proximal winged hub. Certain CVC configurations are power injectable. The CVC may be packaged as a convenience kit with various other components which may include a dilator, inner catheter, wire guide, access needle, injection caps, clamps, catheter securement device, connecting tube, and other convenience accessories. The subject device inner catheter, supplied with the 9 and 10 French subject device catheters, is used to assist advancement of the main catheter over the wire guide. The inner catheter, manufactured from nylon, is designed to lock with the hub of the polyurethane catheter. The subject device dilator, used to dilate the access site during the procedure, is designed with a radiopaque extruded polyethylene shaft and a pre-molded polyethylene proximal hub. It is manufactured with an outside diameter ranging from 3.5 to 12.0 French and has a length between 6 and 11 centimeters. For non-power injectable catheters, the 2.5 French, 3.0 French and 4.0 French catheters are recommended for patients from birth and older (or weighing at least 2.4 kilograms), the 5.0 French catheters are recommended for patients aged 2 years and older (or weighing at least 10 kilograms), the 6.0 French and 6.3 French catheters are recommended for patients aged 4 years and older (or weighing at least 13 kilograms), and the 7.5 French catheters are recommended for patients aged 10 years and older (or weighing at least 50 kilograms). For power injectable catheters, the 4.0 French catheters are recommended for patients from birth and older (or weighing at least 2.4 kilograms), the 5.0 French catheters are recommended for patients aged 2 years and older (or weighing at least 10 kilograms), the 7.0 French and 8.0 French catheters are recommended for patients aged 10 years and older (or weighing at least 50 kilograms),

and the 9.0 French and 10.0 French catheters are recommended for patients aged 21 years and older (adults only).

The Cook Unimpregnated Central Venous Catheter is a short-term device, sterilized by ethylene oxide, and intended for single use.

Indications for Use (Non-Power Injectable):

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

Indications for Use (Power Injectable):

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 4.0Fr and 5.0Fr catheters and 10 mL/sec for 7.0, 8.0, 9.0, and 10.0Fr 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.

Comparison to Predicate Device:

The Cook Unimpregnated Central Venous Catheter is substantially equivalent to the predicate device, Cook Central Venous Catheters with or without Heparin (K081113, Cook Incorporated), cleared on July 30, 2008. The subject device is identical to the predicate device in intended use, principle of operation, and fundamental technologies. The differences between the subject device and the predicate device (K081113), including pediatric indication, materials, lumen number, and dimensions do not raise any different questions of safety and/or effectiveness. The substantial equivalence comparison of the subject device to the predicate devices is provided in the table below.
To further support the safety and effectiveness of the subject device dilators, Dilator Sets cleared under K183036 are provided as a reference device.

	PREDICATE DEVICE	SUBJECT DEVICE
	Cook Central Venous Catheters with or without Heparin (K081113)	**Cook Unimpregnated Central Venous Catheter**
Regulation	21 CFR §880.5200	IDENTICAL TO PREDICATE
Product Code	FOZ Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	IDENTICAL TO PREDICATE
Classification	II	IDENTICAL TO PREDICATE
Indications for Use	The Cook 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 device is a short-term use catheter. *The flow rate of the Cook Central Venous Catheters may not exceed 10 mL/sec.	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 Cook unimpregnated Central Venous Catheter (Non-Power Injectable) is intended for adult and pediatric populations.

<table>
<tr><td></td><td></td><td>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.</td></tr>
<tr><td>Patient Population</td><td>Not specified</td><td><table><tr><th>Catheter Size</th><th>Recommended Minimum Age / Weight</th></tr><tr><td>2.5Fr</td><td>Birth / < 2.4 kg</td></tr><tr><td>3.0Fr
4.0Fr</td><td>Birth / 2.4 kg</td></tr><tr><td>5.0Fr</td><td>2 yrs / 10 kg</td></tr><tr><td>6.3Fr</td><td>4 yrs / 13 kg</td></tr><tr><td>7.0Fr
7.5Fr
8.0Fr</td><td>10 yrs / 50 kg</td></tr><tr><td>9.0Fr
10.0Fr</td><td>21 yrs (adult only)</td></tr></table></td></tr>
<tr><td>Device is for One-Time Use</td><td>Yes</td><td>IDENTICAL TO PREDICATE</td></tr>
<tr><td>Catheter Placement Method</td><td>Percutaneous via Seldinger technique</td><td>IDENTICAL TO PREDICATE</td></tr>
<tr><td>Catheter Tip Target Anatomy</td><td>SVC-RA junction</td><td>IDENTICAL TO PREDICATE</td></tr>
</table>

Catheter Tip Location Confirmation Method	ECG/Ultrasound/Fluoroscopy	IDENTICAL TO PREDICATE
Catheter Distal End Configuration	Straight and tapered	IDENTICAL TO PREDICATE
Catheter Ink Markings	Yes	IDENTICAL TO PREDICATE
Power Injectable Catheter Configurations (7-10 Fr)	Dual Lumen: 8 Fr Triple Lumen: 7, 9 Fr Five-Lumen: 10 Fr	IDENTICAL TO PREDICATE
Upper Pressure Limit for Power Injection (7-10 Fr)	325 psi	IDENTICAL TO PREDICATE
Power Injectable Catheter Configurations (4-5 Fr)	Not applicable	Dual Lumen: 4, 5 Fr Triple Lumen: 5 Fr
Upper Pressure Limit for Power Injection (4-5 Fr)	Not applicable	250 psi
Catheter Shaft Material	Polyurethane	Polyethylene Ethylene-Vinyl Acetate Polyurethane
Catheter Lumen Number	2, 3, 5	1, 2, 3, 5
Lumen Shape	Round, Crescent	Round, D-shaped
Catheter Outer Diameter (Fr.)	Dual – 8 Fr Triple – 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
Catheter Length	15 to 25 cm	5 to 26.5 cm
Inner Catheter Material	Nylon	IDENTICAL TO PREDICATE
Inner Catheter Outer Diameter	4.3 French	4.0 French
Dilator Size (French)	3.0-12.0	3.5-12.0
Dilator Tip OD (inch)	0.038-0.157	0.046-0.157
Dilator Tip ID (inch)	0.025-0.043	IDENTICAL TO PREDICATE
Dilator Material	Polyethylene	IDENTICAL TO PREDICATE
Dilator Length (centimeters)	4.0-11.0	IDENTICAL TO PREDICATE
Dilator Endhole Diameter (inch)	0.018, 0.021, 0.025, or 0.035	IDENTICAL TO PREDICATE

Main Accessory Components	Wire Guide Introducer Needle Dilator Syringe Injection Caps	Wire Guide Introducer Needle Dilator Syringe Injection Caps Inner Catheter Clamps Moveable Suture Wing
Packaging	PETG Tray with Tyvek Lidstock	IDENTICAL TO PREDICATE
Sterilization Method	EtO	IDENTICAL TO PREDICATE
Sterility Assurance Level	10^{-6}	IDENTICAL TO PREDICATE

Intended Use

The predicate and subject devices are short-term use (less than 30 days) central venous catheters (CVC). They have the same intended use, which is inserted into the patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously.

Indications for Use

- **Function of catheter:** Both the predicate and subject devices are indicated for continuous or intermittent drug infusions, central venous blood pressure monitoring (CVP), acute hyperalimentation, blood sampling, delivery of whole blood or blood products, and power injection of contrast media. The subject device is also indicated for simultaneous, separate infusion of drugs (for multi-lumen catheters only). Since a multi-lumen CVC allows simultaneous and separate infusion of drugs by utilizing individual lumens, this additional language in the indications for use statement does not raise different questions of safety and/or effectiveness when compared to the predicate device.
- **Power injection of contrast media:** All French sizes of the predicate device catheter are indicated for power injection of contrast media, and the flow rate may not exceed 10 mL/sec. The subject device includes catheters that are indicated for power injection of contrast media and catheters that are not indicated for power injection of contrast media. For the power injectable catheters, the flow rate may not exceed 3.0 mL/sec for the 4.0 and 5.0 French catheters and 10 mL/sec for the 7.0, 8.0, 9.0, and 10.0 French catheters. These flow rate limits were established from performance testing using subject device catheters with power injector pressures set at the maximum safety cut-off pressure to ensure safe and effective use of the catheters. For the 4.0 and 5.0 French subject device catheters, the

maximum flow rate (3.0 mL/sec) is within the range of a reference device, the Turbo-Ject Peripherally Inserted Central Venous Catheter (PICC) (K072625), which is available in 4.0 and 5.0 French with maximum flow rates ranging from 3 mL/sec to 7.0 mL/sec. For the 7.0, 8.0, 9.0, and 10.0 French subject device catheters, the maximum flow rate (10 mL/sec) is identical to the predicate. The 2.5, 3.0, 6.3, and 7.5 French subject device catheters are not indicated for power injection of contrast media. The non-power injectable subject device catheters, not having an indication for power injection of contrast media does not raise different questions of safety and/or effectiveness when comparing to the predicate. In addition, the subject device will include two Instructions for Use (IFU) booklets; one for the power injectable catheters and one for the non-power injectable catheters. For the non-power injectable catheters, the IFU states the following in the Warning Section: "Do not power inject contrast medium through catheter. Catheter rupture may result."

- **Patient Population:** The predicate device does not specify age / weight recommendation for patient use. The subject device is indicated for adult and pediatric patients. Central venous catheters are critical in establishing a vascular access to sample blood, monitor blood pressure, and administer fluids intravenously, and these functions apply to both adult and pediatric patients. It is common in clinical practice to use relatively small CVCs in pediatric patients because their blood vessels are generally smaller comparing to adult patients. When establishing the minimum age and weight of patients for each catheter French size, the approximate diameters of femoral veins from a wide range of pediatric patients (from preterm neonates to 19 years old) have been carefully considered to ensure each French size is appropriate for use in patients with the associated minimum age/weight.

Overall, the subject and predicate devices have the same intended use and similar indications for use.

Technological Characteristics:

The subject device Cook Unimpregnated Central Venous Catheter was subjected to applicable testing to assure design and performance under the testing parameters. The following tests have been conducted to ensure design and performance under the specified testing parameters:

Performance:

- Catheter Shaft Tensile (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 Fr catheters, 10 N for 4 and 5 Fr catheters, and 15 N for catheters larger than 5 Fr in accordance with BS EN ISO 10555-1:2013. The acceptance criteria were met.
- Catheter Sideport Tensile (Aged) – The peak tensile load for the sideport section of the catheter shall be greater than or equal to 10 N for 4 and 5 Fr catheters, and 15 N for catheters larger than 5 Fr in accordance with BS EN ISO 10555-1:2013. The acceptance criteria were met.
- Catheter Shaft-to-Hub Tensile (Aged) – The peak tensile load for the shaft-to-hub section of the catheter shall be greater than or equal to 5 N for 2.5 and 3 Fr catheters, 10 N for 4 and 5 Fr catheters, and 15 N for catheters larger than 5 Fr in accordance with BS EN ISO 10555-1:2013. The acceptance criteria were met.
- Catheter Shaft-to-Manifold Tensile (Aged) – The peak tensile load for the shaft-to-manifold section of the catheter shall be greater than or equal to 10 N for 4 and 5 Fr catheters, and 15 N for catheters larger than 5 Fr in accordance with BS EN ISO 10555-1:2013. The acceptance criteria were met.
- Catheter Manifold-to-Extension Tube Tensile (Aged) – The peak tensile load for the manifold-to-extension tube section of the catheter shall be greater than or equal to 10 N for 4 and 5 Fr catheters, and 15 N for catheters larger than 5 Fr in accordance with BS EN ISO 10555-1:2013. The acceptance criteria were met.
- Catheter Extension Tube-to-Hub Tensile (Aged) – The peak tensile load for the extension tube-to-hub section of the catheter shall be greater than or equal to 10 N for 4 and 5 Fr catheters, and 15 N for catheters larger than 5 Fr in accordance with BS EN ISO 10555-1:2013. The acceptance criteria were met.
- Catheter Liquid Leakage (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 (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 Radius (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 Gravity Flow Rate (Time-Zero) – The flow rate of the test articles will be characterized when tested in accordance with Annex E of BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Static Burst (Aged) – The catheter failure pressure during static burst was characterized for the test articles when tested in accordance with Annex F of BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Hub Pressure (Power Injection) (Aged) – The peak hub pressure of the power injectable lumen for each specimen type for the test articles when tested in accordance with Annex G of BS EN ISO 10555-1. The acceptance criterion was met.
- Inner Catheter Shaft Tensile (Time-Zero) – The peak tensile load for the shaft section of the inner catheter shall be greater than or equal to 5 N for 3 Fr catheters and 10 N for 4 Fr catheters in accordance with BS EN ISO 10555-1:2013. The acceptance criteria were met.
- Inner Catheter Hub-to-Shaft Tensile (Time-Zero) – The peak tensile load for the hub-to-shaft section of the inner catheter shall be greater than or equal to 5 N for 3 Fr catheters and 10 N for 4 Fr catheters in accordance with BS EN ISO 10555-1:2013. The acceptance criteria were met.
- Dilator Hub-to-Shaft Tensile (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, 10 N for 3.5, 4.0, 5.0, and 5.5 Fr dilators, and 15 N for dilators larger than 5.5 Fr, in accordance with BS EN ISO 11070. The acceptance criterion was met.
- Dilator and Wire Guide Compatibility Analysis – Each unique dilator French size shall be compatible with the correlating wire guide.
- Catheter Hub Luer Compatibility Analysis – The catheter hub subject device was tested in accordance with the test methods specified in ISO 594-1:1986 and ISO 594-2:1998.

<u>Packaging and Sterility Testing:</u>

- Dye penetration testing per ASTM F1929-15
- Seal strength testing per ASTM F88/F88M-15

- Sterilization validation testing per ISO 11135-1:2014

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.

Conclusion:

The results of these tests confirm that the Cook Unimpregnated Central Venous Catheter 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 as compared to the predicate device. The submitted information supports the determination that the subject device is substantially equivalent to the primary predicate device, Cook Central Venous Catheters with or without Heparin (K081113).