



April 9, 2025

Becton Dickinson Inc. (BD)  
Connor Dahl  
Staff Regulatory Affairs Specialist  
605 North 5600 West  
Salt Lake City, Utah 84116

Re: K242429

Trade/Device Name: CentroVena Central Venous Catheter (CVC) with the CentroVena One Insertion System  
Regulation Number: 21 CFR 880.5200  
Regulation Name: Intravascular Catheter  
Regulatory Class: Class II  
Product Code: SEF  
Dated: March 6, 2025  
Received: March 7, 2025

Dear Connor Dahl:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, reading "David Wolloscheck". The signature is written in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

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

## Indications for Use

510(k) Number (if known)  
K242429

Device Name

CentroVena Central Venous Catheter (CVC) with the CentroVena One Insertion System

Indications for Use (Describe)

CentroVena Central Venous Catheter (CVC)

Acute central venous catheters are indicated to provide short term access (< 30 days) to the central venous system. They are designed for administering IV fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.

7F Triple Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Triple Lumen, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Triple Lumen Catheter Size, 30 cm Catheter Length, Distal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Triple Lumen Catheter Size, 30 cm Catheter Length, Medial/Proximal Lumen, 7 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

CentroVena One Insertion System

The CentroVena One Insertion System is indicated to facilitate the insertion of the included central venous catheters.

Acute central venous catheters are indicated to provide short term access (< 30 days) to the central venous system. They are designed for administering IV fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.

7F Triple Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Triple Lumen, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Triple Lumen Catheter Size, 30 cm Catheter Length, Distal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Triple Lumen Catheter Size, 30 cm Catheter Length, Medial/Proximal Lumen, 7 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

---

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](mailto: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."*

**K242429 – 510k Summary – The CentroVena Central Venous Catheter (CVC)**  
**with the CentroVena One Insertion System**

**21 CFR 807.92(a)**

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part(I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based on is presented in the following table.

|                           |                      |                                                                                      |
|---------------------------|----------------------|--------------------------------------------------------------------------------------|
| <b>General Provisions</b> | Submitter Name:      | Becton Dickinson Inc.(BD)                                                            |
|                           | Submitter Address:   | 605 North 5600 West Salt<br>Lake City, UT 84116                                      |
|                           | Contact Person:      | Connor Dahl -Staff Regulatory Affairs Specialist                                     |
|                           | Telephone Number:    | 801.522.5000                                                                         |
|                           | Fax Number:          | 801.522.5425                                                                         |
|                           | Date of Preparation: | 04/09/2025                                                                           |
| <b>Subject Device</b>     | Trade Name(s):       | CentroVena Central Venous Catheter (CVC) with the<br>CentroVena One Insertion System |
|                           | Common Name:         | Central venous catheter with manual insertion system                                 |
|                           | Classification Name: | Catheter, Intravascular, Therapeutic, Short-Term Less than<br>30 days                |
|                           | Class:               | 2                                                                                    |
|                           | Regulation Number:   | 21 CFR 880.5200                                                                      |
|                           | Product Code:        | SEF                                                                                  |
|                           | Classification Panel | General Hospital                                                                     |

|                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Predicate Device</b>    | <p>Predicate Trade Name: BD Acute Central Line</p> <p>Classification Name: Catheter, Intravascular, Therapeutic, Short-Term Less than 30 days</p> <p>Class: 2</p> <p>Product Code: FOZ</p> <p>Regulation Number: 21 CFR 880.5200</p> <p>Premarket Notification #: K190855</p> <p>Manufacturer: Bard Access Systems, Inc</p> <p>Classification Panel: General Hospital</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Device Description</b>  | <p>CentroVena Central Venous Catheters are power-injectable, constructed of medical grade polyurethane and designed for insertion into the central venous system. The central venous catheters are radiopaque and have a soft tip that is more pliable than the catheter body. Each catheter is provided in a sterile package with other applicable insertion kit accessories.</p> <p>The CentroVena One Insertion System integrates the essential components for placing central venous catheters. It combines an introducer needle with a passive needle tip safety mechanism, syringe, guidewire, and self-dilating catheter into one unit. The device is preassembled and also has an integrated drape clip permanently attached to the guidewire designed to keep the system organized in the sterile field and prevent guidewire embolism.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Intended Use</b>        | <p>BD Acute Central Lines are intended for short-term access to the central venous system for intravenous therapy and blood sampling.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Indications for Use</b> | <p>CentroVena Central Venous Catheter (CVC)</p> <p>Acute central venous catheters are indicated to provide short term access (&lt; 30 days) to the central venous system. They are designed for administering IV fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.</p> <p>7F Triple Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Triple Lumen, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Triple Lumen Catheter Size, 30 cm Catheter Length, Distal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Triple Lumen Catheter Size, 30 cm Catheter Length, Medial/Proximal Lumen, 7 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> |

### CentroVena One Insertion System

The CentroVena One Insertion System is indicated to facilitate the insertion of the included central venous catheters.

Acute central venous catheters are indicated to provide short term access (< 30 days) to the central venous system. They are designed for administering IV fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.

7F Triple Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Triple Lumen, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Triple Lumen Catheter Size, 30 cm Catheter Length, Distal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Triple Lumen Catheter Size, 30 cm Catheter Length, Medial/Proximal Lumen, 7 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting

Technological characteristics of the subject, the CentroVena Central Venous Catheter (CVC) with the CentroVena One Insertion System, are substantially equivalent with respect to basic design, function and fundamental scientific technology to those of the cited predicate device.

Key differences in the subject device when compared to the predicate device are as follows:

- Design: Catheter Tip Shape and Geometry changed from the predicate
- Materials: Polyurethane Formulation changed to achieve tapered tip geometry
- Labeling: Contraindications previously included with the predicate device, were changed to precautions in the subject device
- Packaging: CentroVena One Insertion System Kits were introduced and will be packaged in sterile, single-use sealed trays with an additional sealed header bag that was previously not included with the predicate.

The following table provides a comparison between the subject and predicate devices.

| Attribute                                                                                                                                                  | Subject Device<br><br>CentroVena Central Venous Catheter (CVC)<br>with the CentroVena One Insertion System                                                                                                                                                                                                                                                                           | Predicate Device<br><br>BD Acute Central Line                                                                                                                                                                                                                                                                                                                                                                                                                                       | Equivalency                                                                                                                                                                                                                                                                                                                                                                              |               |                           |                                         |                           |                                         |                 |                 |        |         |         |                 |        |       |        |        |                 |        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------------------|-----------------------------------------|---------------------------|-----------------------------------------|-----------------|-----------------|--------|---------|---------|-----------------|--------|-------|--------|--------|-----------------|--------|
| Owner                                                                                                                                                      | Becton Dickinson Inc. (BD)                                                                                                                                                                                                                                                                                                                                                           | Becton Dickinson Inc. (BD)                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Equivalent                                                                                                                                                                                                                                                                                                                                                                               |               |                           |                                         |                           |                                         |                 |                 |        |         |         |                 |        |       |        |        |                 |        |
| Indications for Use                                                                                                                                        | CentroVena Central Venous Catheter (CVC)<br><br>Acute central venous catheters are indicated to provide short term access (< 30 days) to the central venous system. They are designed for administering IV fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media. | Acute central venous catheters are indicated to provide short-term access (< 30 days) to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.                                                                                                                                              | Equivalent<br><br>The Indications for use of the subject catheter are equivalent. The inclusion of the insertion device, which serves to facilitate placement of the parent catheter, does not change the overall intended use of the parent device and does not raise new or different questions of safety or effectiveness compared to the predicate, BD Acute Central Line Basic Kit. |               |                           |                                         |                           |                                         |                 |                 |        |         |         |                 |        |       |        |        |                 |        |
|                                                                                                                                                            | 7F Triple Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting                                                                                                                                                                                                                     | <table><tr><th>Catheter Size</th><th>Catheter Length</th><th>Lumen</th><th>Power Injection Flow Rate</th><th>Maximum Power Injector Pressure Setting</th></tr><tr><td rowspan="4">7F Triple Lumen</td><td rowspan="2">16 cm and 20 cm</td><td>Distal</td><td>10 mL/s</td><td rowspan="4">325 psi</td></tr><tr><td>Medial/Proximal</td><td>9 mL/s</td></tr><tr><td rowspan="2">30 cm</td><td>Distal</td><td>9 mL/s</td></tr><tr><td>Medial/Proximal</td><td>7 mL/s</td></tr></table> |                                                                                                                                                                                                                                                                                                                                                                                          | Catheter Size | Catheter Length           | Lumen                                   | Power Injection Flow Rate | Maximum Power Injector Pressure Setting | 7F Triple Lumen | 16 cm and 20 cm | Distal | 10 mL/s | 325 psi | Medial/Proximal | 9 mL/s | 30 cm | Distal | 9 mL/s | Medial/Proximal | 7 mL/s |
|                                                                                                                                                            | Catheter Size                                                                                                                                                                                                                                                                                                                                                                        | Catheter Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                          | Lumen         | Power Injection Flow Rate | Maximum Power Injector Pressure Setting |                           |                                         |                 |                 |        |         |         |                 |        |       |        |        |                 |        |
| 7F Triple Lumen                                                                                                                                            | 16 cm and 20 cm                                                                                                                                                                                                                                                                                                                                                                      | Distal                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 10 mL/s                                                                                                                                                                                                                                                                                                                                                                                  | 325 psi       |                           |                                         |                           |                                         |                 |                 |        |         |         |                 |        |       |        |        |                 |        |
|                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                      | Medial/Proximal                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 9 mL/s                                                                                                                                                                                                                                                                                                                                                                                   |               |                           |                                         |                           |                                         |                 |                 |        |         |         |                 |        |       |        |        |                 |        |
|                                                                                                                                                            | 30 cm                                                                                                                                                                                                                                                                                                                                                                                | Distal                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 9 mL/s                                                                                                                                                                                                                                                                                                                                                                                   |               |                           |                                         |                           |                                         |                 |                 |        |         |         |                 |        |       |        |        |                 |        |
|                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                      | Medial/Proximal                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 7 mL/s                                                                                                                                                                                                                                                                                                                                                                                   |               |                           |                                         |                           |                                         |                 |                 |        |         |         |                 |        |       |        |        |                 |        |
| 7F Triple Lumen, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting |                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                          |               |                           |                                         |                           |                                         |                 |                 |        |         |         |                 |        |       |        |        |                 |        |
| 7F Triple Lumen Catheter Size, 30 cm Catheter Length, Distal Lumen, 9 mL/s Power Injection Flow                                                            |                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                          |               |                           |                                         |                           |                                         |                 |                 |        |         |         |                 |        |       |        |        |                 |        |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
|  | <p>Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Triple Lumen Catheter Size, 30 cm Catheter Length, Medial/Proximal Lumen, 7 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>CentroVena One Insertion System</p> <p>The CentroVena One Insertion System is indicated to facilitate the insertion of the included central venous catheters.</p> <p>Acute central venous catheters are indicated to provide short term access (&lt; 30 days) to the central venous system. They are designed for administering IV fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.</p> <p>7F Triple Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Triple Lumen, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> |  |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                | <p>7F Triple Lumen Catheter Size, 30 cm Catheter Length, Distal Lumen, 9 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Triple Lumen Catheter Size, 30 cm Catheter Length, Medial/Proximal Lumen, 7 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Distal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> <p>7F Dual Lumen Catheter Size, 16 cm and 20 cm Catheter Length, Medial/Proximal Lumen, 10 mL/s Power Injection Flow Rate, 325 psi Maximum Power Injector Pressure Setting</p> |                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Commercial Name</b>         | CentroVena Central Venous Catheter (CVC) with the CentroVena One Insertion System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | BD Acute Central Line                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Catheter Configurations</b> | <p>7 Fr Triple Lumen x 16 cm</p> <p>7 Fr Triple Lumen x 20 cm</p> <p>7 Fr Triple Lumen x 30 cm</p> <p>7 Fr, Dual Lumen x 16 cm</p> <p>7 Fr, Dual Lumen x 20 cm</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>7 Fr Triple Lumen x 16 cm</p> <p>7 Fr Triple Lumen x 20 cm</p> <p>7 Fr Triple Lumen x 30 cm</p> | <p>Equivalent</p> <p>While a dual lumen configuration was not included in the predicate, an additional dual lumen configuration does not raise new or different questions of safety or effectiveness. The dual lumen was evaluated using the same methods as the triple lumen and function in equivalent ways. Testing was performed and submitted on both configurations when the triple lumen was not the worst-case scenario. Results from testing did not raise any new concerns of safety and effectiveness.</p> |

|                               |                                                                                                                                                                                          |                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                               |                                                                                                                                                                                          |                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Principle of Operation</b> | Same                                                                                                                                                                                     | Conduit for fluids in and out of the central venous system                                                                                                                                  | Equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Duration of Use</b>        | Same                                                                                                                                                                                     | Short term (<30 days)                                                                                                                                                                       | Equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Insertion Site</b>         | Same                                                                                                                                                                                     | Jugular, subclavian or femoral veins                                                                                                                                                        | Equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Means of Insertion</b>     | <ul style="list-style-type: none"> <li>• Percutaneous insertion using Seldinger Technique (Basic)</li> <li>• Percutaneous insertion using the CentroVena One Insertion System</li> </ul> | <ul style="list-style-type: none"> <li>• Percutaneous insertion using Seldinger Technique.(Basic)</li> <li>• The Centrovena One Insertion System was not included with predicate</li> </ul> | <p>Equivalent</p> <p>The insertion device was not a means of insertion in the predicate device. However, the insertion device is comprised of components used in the predicate device traditional (Basic) Seldinger kits. This combination of kit components was evaluated using human factors and risk management approaches to show that there are no additional or increased risks in placing the subject CentroVena CVC with the insertion device compared to a traditional placement. Therefore, the addition of an insertion tool does not raise any new questions of safety or effectiveness.</p> |
| <b>Catheter Tip</b>           | Tapered Tip                                                                                                                                                                              | Blunt Tip                                                                                                                                                                                   | <p>Equivalent</p> <p>The polyurethane was reformulated to achieve the tapered tip geometry The modified tip geometry was evaluated with functional performance testing and did not raise any new questions of safety or effectiveness.</p>                                                                                                                                                                                                                                                                                                                                                               |

|                                        |                                                                 |                                                                             |                                                                                                                                                                                                                                                    |
|----------------------------------------|-----------------------------------------------------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Catheter Tip Placement Location</b> | Same                                                            | Central venous system, with lower 1/3 of superior vena cava (SVC) preferred | Equivalent                                                                                                                                                                                                                                         |
| <b>Skives on Catheter Shaft</b>        | Skives are moved back on the catheter shaft due to tapered tip. | Skives are towards the front of the catheter                                | <p>Equivalent</p> <p>Movement of the skives distally from the tip of the catheter was due to a change in tip geometry and was evaluated by functional and performance testing and does not raise any new questions of safety or effectiveness.</p> |



|  |                                                                                                                                                                                                                                                                                                                                                  |                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                        |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p><u>CentroVena One Insertion System Materials</u></p> <p><u>Syringe:</u> Polypropylene</p> <p><u>Guidewire with J-Tip:</u><br/>Nitinol/Stainless Steel</p> <p><u>White Hub:</u> Polycarbonate</p> <p><u>Gray Release Tabs:</u><br/>Polycarbonate</p> <p><u>Introducer Needle &amp; Integrated Sheath:</u><br/>Stainless Steel/Polyurethane</p> | <p>There was no insertion system device included in Predicate</p> | <p>The components of the CentroVena One Insertion System were not included in the predicate as there was no insertion systems device included in the predicate.</p> <p>The intended use of the syringe will remain the same as the predicate as the device will still be used to inject fluids into, or withdraw fluids from, the body as per the definition described by FDA regulation 880.5860.</p> |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Power Injection<br/>Maximum Flow<br/>Rate</b> | <p>Triple Lumen:<br/>16 and 20 cm lengths:</p> <ul style="list-style-type: none"> <li>• Distal (17 Ga.) – 10 mL/sec</li> <li>• Medial (18 Ga.) – 9 mL/sec</li> <li>• Proximal (18 Ga.) – 9 mL/sec</li> </ul> <p>30 cm length:</p> <ul style="list-style-type: none"> <li>• Distal (17 Ga.) – 9 mL/sec</li> <li>• Medial (18 Ga.) – 7 mL/sec</li> <li>• Proximal (18 Ga.) – 7 mL/sec</li> </ul> <p>Dual Lumen:<br/>16 and 20 cm lengths:</p> <ul style="list-style-type: none"> <li>• Distal (15 Ga.) – 10 mL/sec</li> <li>• Proximal (17 Ga.) – 10 mL/sec</li> </ul> | <p>Triple Lumen:<br/>16 and 20 cm lengths:</p> <ul style="list-style-type: none"> <li>• Distal (17 Ga.) – 10 mL/sec</li> <li>• Medial (18 Ga.) – 9 mL/sec</li> <li>• Proximal (18 Ga.) – 9 mL/sec</li> </ul> <p>30 cm length:</p> <ul style="list-style-type: none"> <li>• Distal (17 Ga.) – 9 mL/sec</li> <li>• Medial (18 Ga.) – 7 mL/sec</li> <li>• Proximal (18 Ga.) – 7 mL/sec</li> </ul> | <p>Equivalent</p> <p>While a dual lumen configuration was not included in the predicate, an additional dual lumen configuration does not raise new or different questions of safety or effectiveness. The dual lumen was evaluated using the same methods as the triple lumen and function in equivalent ways. Testing was performed and submitted on both configurations when the triple lumen was not the worst-case scenario. Results from testing did not raise any new concerns of safety and effectiveness.</p> |
| <b>Kit<br/>Packaging</b>                         | <p>CentroVena Basic (Seldinger) Kits</p> <ul style="list-style-type: none"> <li>• Thermoformed HIPS tray sealed with a Tyvek lid</li> </ul> <p>CentroVena One Insertion System Kits</p> <ul style="list-style-type: none"> <li>• Thermoformed HIPS tray within a sealed header bag sealed with a Tyvek lid</li> </ul>                                                                                                                                                                                                                                                | <p>Basic (Seldinger) Kits</p> <ul style="list-style-type: none"> <li>• Thermoformed HIPS tray sealed with a Tyvek lid</li> </ul> <p>Insertion System Kits</p> <ul style="list-style-type: none"> <li>• Not Applicable to Predicate Device</li> </ul>                                                                                                                                           | <p>Equivalent</p> <p>Additional header bag for insertion kits have no impact on substantial equivalence as the kit configuration was not utilized in the predicate device.</p>                                                                                                                                                                                                                                                                                                                                        |
| <b>Sterility</b>                                 | Same                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Provided Sterile                                                                                                                                                                                                                                                                                                                                                                               | Equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

The technological differences listed above were evaluated using industry consensus standards, and as defined in the risk assessment. The modifications to subject device when compared to the cited predicate device have been evaluated and demonstrated through functional performance testing to have no new or different concerns regarding safety and effectiveness.

The following performance tests were conducted in determining substantial equivalence of the CentroVena Central Venous Catheter (CVC) with the CentroVena One Insertion System to the predicate BD Acute Central Line:

|                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Testing Relating to the CentroVena Central Venous Catheter (CVC)</b>                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Reference Standard: ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Biocompatibility Testing</b>                                                                                                                          | <p>Tests to confirm that the catheter is free from biological hazard.</p> <p>Testing Performed includes:</p> <ul style="list-style-type: none"> <li>• Cytotoxicity</li> <li>• Sensitization</li> <li>• Irritation or Intracutaneous Reactivity</li> <li>• Acute Systemic Toxicity</li> <li>• Pyrogenicity</li> <li>• Subchronic Systemic Toxicity</li> <li>• Genotoxicity</li> <li>• Hemocompatibility</li> <li>• Implantation</li> </ul>                                                          |
| <b>Reference Standard: ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</b>                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Test(s)</b>                                                                                                                                           | <ul style="list-style-type: none"> <li>• Clamp Engagement</li> <li>• Leak Test</li> <li>• Dimensional Test</li> <li>• Implantable Length</li> <li>• Extension Leg Length</li> <li>• Burst Test</li> <li>• Hydraulic Catheter Burst Test</li> <li>• Power Injection Conditioning</li> <li>• Gravity Flow</li> <li>• Luer to Extension Leg Tensile Test</li> <li>• Extension Leg to Catheter Junction Tensile</li> <li>• Catheter Junction to Shaft Tensile</li> <li>• Shaft Tensile Test</li> </ul> |
| <b>Reference Standard: ASTM F640-2020 – Standard Test Methods for Radiopacity of Plastics for Medical Use</b>                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Test(s)</b>                                                                                                                                           | <ul style="list-style-type: none"> <li>• Radiopacity</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Reference Standard: ASTM F 756-17 Standard Practice for Assessment of Hemolytic Properties of Materials</b>                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Test(s)</b>                                                                                                                                           | <ul style="list-style-type: none"> <li>• Mechanical Hemolysis</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Reference Standard: ISO 10555-3:2013 – Intravascular catheters – Sterile and single-use catheters – Part 3: Central venous catheters</b>              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

|  |                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                         |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Test(s)                                                                                                                                                                                                                                                                                                                 | <ul style="list-style-type: none"> <li>• Tip Tensile</li> <li>• Catheter Printing</li> </ul>                                                                                                                                                                                                                                                                            |
|  | Reference Standard: FDA Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, 1995                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                         |
|  | Test(s)                                                                                                                                                                                                                                                                                                                 | <ul style="list-style-type: none"> <li>• Catheter Collapse Test</li> <li>• Shaft Tensile and Elongation Test</li> <li>• Suture Wing Integrity Test</li> <li>• Priming Volume</li> <li>• OD Swell</li> <li>• Tip Stability Test</li> <li>• Guidewire Drag Test</li> </ul>                                                                                                |
|  | Reference Standards: <i>ISO 80369-1:2018 Small-bore connectors for liquids and gases in healthcare applications – Part 1: General Requirements</i> and <i>ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications</i> |                                                                                                                                                                                                                                                                                                                                                                         |
|  | Test(s)                                                                                                                                                                                                                                                                                                                 | <ul style="list-style-type: none"> <li>• Dimensions</li> <li>• ISO Luer Functional Performance</li> </ul>                                                                                                                                                                                                                                                               |
|  | Reference Standard: FDA Guidance on Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, 2023                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                         |
|  | Test(s)                                                                                                                                                                                                                                                                                                                 | <ul style="list-style-type: none"> <li>• MR Testing</li> </ul>                                                                                                                                                                                                                                                                                                          |
|  | Reference Standard: USP <788>:2012 Small Volume Injections – Particulate Matter in Injections                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                         |
|  | Test(s)                                                                                                                                                                                                                                                                                                                 | <ul style="list-style-type: none"> <li>• Particulate Testing</li> </ul>                                                                                                                                                                                                                                                                                                 |
|  |                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                         |
|  | <b>Testing Relating to the CentroVena One Insertion System</b>                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
|  | Reference Standard: ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                         |
|  | Biocompatibility Testing                                                                                                                                                                                                                                                                                                | <p>Tests to confirm that the system is free from biological hazard.</p> <p>Testing Performed includes:</p> <ul style="list-style-type: none"> <li>• Cytotoxicity</li> <li>• Sensitization</li> <li>• Irritation or Intracutaneous Reactivity</li> <li>• Acute Systemic Toxicity</li> <li>• Pyrogenicity</li> <li>• Genotoxicity</li> <li>• Hemocompatibility</li> </ul> |
|  | Reference Standard: FDA Guidance Document, 2019, Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                         |

|                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--|----------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|--|----------------|--------------------------------------------------------------------------|-------------------------------------------------------------------------|--|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--|----------------|------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|--|----------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|                                                                                                                                                                                                                                   | <table> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>• Guidewire Dimensions</li> <li>• Guidewire Corrosion Resistance</li> <li>• Guidewire Particulate</li> <li>• Guidewire Tensile</li> <li>• Guidewire Kink Resistance</li> <li>• Guidewire Torque Strength</li> <li>• Guidewire Tip Flexibility</li> <li>• Simulated Use Conditioning</li> </ul> </td></tr> </table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Test(s)</b>                                                                                                  | <ul style="list-style-type: none"> <li>• Guidewire Dimensions</li> <li>• Guidewire Corrosion Resistance</li> <li>• Guidewire Particulate</li> <li>• Guidewire Tensile</li> <li>• Guidewire Kink Resistance</li> <li>• Guidewire Torque Strength</li> <li>• Guidewire Tip Flexibility</li> <li>• Simulated Use Conditioning</li> </ul> |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Test(s)</b>                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Guidewire Dimensions</li> <li>• Guidewire Corrosion Resistance</li> <li>• Guidewire Particulate</li> <li>• Guidewire Tensile</li> <li>• Guidewire Kink Resistance</li> <li>• Guidewire Torque Strength</li> <li>• Guidewire Tip Flexibility</li> <li>• Simulated Use Conditioning</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
|                                                                                                                                                                                                                                   | <table> <tr> <td colspan="2"><b>Reference Standard: ISO 11070:2014 Sterile Single-Use Intravascular Introducers, Dilators and Guidewires</b></td></tr> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>• Effective Needle Length</li> <li>• Guidewire and Sheath Radiopacity</li> <li>• Corrosion Resistance</li> <li>• Guidewire Surface Defects</li> <li>• Sheath Surface</li> <li>• Lubricant</li> <li>• Needle / Hub Separation Force</li> <li>• Sheath Separation Force</li> <li>• Guidewire Uncoiling</li> <li>• Guidewire Shear Force, Fracture</li> <li>• Guidewire Shear Force, Flexure</li> <li>• Guidewire Peak Tensile Force</li> <li>• Guidewire Size Designation</li> <li>• Needle Size Designation</li> </ul> </td></tr> <tr> <td colspan="2"><b>Reference Standard: ASTM F640-20 Radiopacity</b></td></tr> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>• Radiopacity</li> </ul> </td></tr> <tr> <td colspan="2"><b>Reference Standard: ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials</b></td></tr> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>• Mechanical Hemolysis</li> </ul> </td></tr> <tr> <td colspan="2"><b>Reference Standard: FDA Guidance, 2005, Sharps Injury Prevention</b></td></tr> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>• Needle Point Exposure Limit</li> <li>• Needle Safety and Reliability</li> <li>• Needle Use</li> <li>• Needle Reliability</li> <li>• Needle Tip Access</li> </ul> </td></tr> <tr> <td colspan="2"><b>Reference Standard: ISO 10555-1:2013 Intravascular Catheters – Sterile and Single-Use Catheters General Requirements</b></td></tr> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>• Sheath Tip</li> <li>• Sheath Surface</li> </ul> </td></tr> <tr> <td colspan="2"><b>Reference Standard: ISO 10555-5:2008 Intravascular Catheters – Sterile and Single-Use Catheters Over-Needle Peripheral Catheters</b></td></tr> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>• Needle / Sheath Outer Diameter</li> <li>• Lie Distance</li> </ul> </td></tr> <tr> <td colspan="2"><b>Reference Standard: ISO 23908:2011 Sharps Injury Protection – Requirements and Test Methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.</b></td></tr> </table> | <b>Reference Standard: ISO 11070:2014 Sterile Single-Use Intravascular Introducers, Dilators and Guidewires</b> |                                                                                                                                                                                                                                                                                                                                       | <b>Test(s)</b> | <ul style="list-style-type: none"> <li>• Effective Needle Length</li> <li>• Guidewire and Sheath Radiopacity</li> <li>• Corrosion Resistance</li> <li>• Guidewire Surface Defects</li> <li>• Sheath Surface</li> <li>• Lubricant</li> <li>• Needle / Hub Separation Force</li> <li>• Sheath Separation Force</li> <li>• Guidewire Uncoiling</li> <li>• Guidewire Shear Force, Fracture</li> <li>• Guidewire Shear Force, Flexure</li> <li>• Guidewire Peak Tensile Force</li> <li>• Guidewire Size Designation</li> <li>• Needle Size Designation</li> </ul> | <b>Reference Standard: ASTM F640-20 Radiopacity</b> |  | <b>Test(s)</b> | <ul style="list-style-type: none"> <li>• Radiopacity</li> </ul> | <b>Reference Standard: ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials</b> |  | <b>Test(s)</b> | <ul style="list-style-type: none"> <li>• Mechanical Hemolysis</li> </ul> | <b>Reference Standard: FDA Guidance, 2005, Sharps Injury Prevention</b> |  | <b>Test(s)</b> | <ul style="list-style-type: none"> <li>• Needle Point Exposure Limit</li> <li>• Needle Safety and Reliability</li> <li>• Needle Use</li> <li>• Needle Reliability</li> <li>• Needle Tip Access</li> </ul> | <b>Reference Standard: ISO 10555-1:2013 Intravascular Catheters – Sterile and Single-Use Catheters General Requirements</b> |  | <b>Test(s)</b> | <ul style="list-style-type: none"> <li>• Sheath Tip</li> <li>• Sheath Surface</li> </ul> | <b>Reference Standard: ISO 10555-5:2008 Intravascular Catheters – Sterile and Single-Use Catheters Over-Needle Peripheral Catheters</b> |  | <b>Test(s)</b> | <ul style="list-style-type: none"> <li>• Needle / Sheath Outer Diameter</li> <li>• Lie Distance</li> </ul> | <b>Reference Standard: ISO 23908:2011 Sharps Injury Protection – Requirements and Test Methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.</b> |  |
| <b>Reference Standard: ISO 11070:2014 Sterile Single-Use Intravascular Introducers, Dilators and Guidewires</b>                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Test(s)</b>                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Effective Needle Length</li> <li>• Guidewire and Sheath Radiopacity</li> <li>• Corrosion Resistance</li> <li>• Guidewire Surface Defects</li> <li>• Sheath Surface</li> <li>• Lubricant</li> <li>• Needle / Hub Separation Force</li> <li>• Sheath Separation Force</li> <li>• Guidewire Uncoiling</li> <li>• Guidewire Shear Force, Fracture</li> <li>• Guidewire Shear Force, Flexure</li> <li>• Guidewire Peak Tensile Force</li> <li>• Guidewire Size Designation</li> <li>• Needle Size Designation</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Reference Standard: ASTM F640-20 Radiopacity</b>                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Test(s)</b>                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Radiopacity</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Reference Standard: ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials</b>                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Test(s)</b>                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Mechanical Hemolysis</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Reference Standard: FDA Guidance, 2005, Sharps Injury Prevention</b>                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Test(s)</b>                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Needle Point Exposure Limit</li> <li>• Needle Safety and Reliability</li> <li>• Needle Use</li> <li>• Needle Reliability</li> <li>• Needle Tip Access</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Reference Standard: ISO 10555-1:2013 Intravascular Catheters – Sterile and Single-Use Catheters General Requirements</b>                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Test(s)</b>                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Sheath Tip</li> <li>• Sheath Surface</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Reference Standard: ISO 10555-5:2008 Intravascular Catheters – Sterile and Single-Use Catheters Over-Needle Peripheral Catheters</b>                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Test(s)</b>                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Needle / Sheath Outer Diameter</li> <li>• Lie Distance</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |
| <b>Reference Standard: ISO 23908:2011 Sharps Injury Protection – Requirements and Test Methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                     |  |                |                                                                 |                                                                                                               |  |                |                                                                          |                                                                         |  |                |                                                                                                                                                                                                           |                                                                                                                             |  |                |                                                                                          |                                                                                                                                         |  |                |                                                                                                            |                                                                                                                                                                                                                                   |  |

|                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|----------------|-------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|--|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|--|----------------|---------------------------------------------------------------|
|                                                                                                                                                                                                                              | <table> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>Needle Point Exposure Limit</li> <li>Needle Safety and Reliability</li> <li>Needle Use</li> <li>Needle Tip Access</li> </ul> </td></tr> </table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Test(s)</b>                                                                                                     | <ul style="list-style-type: none"> <li>Needle Point Exposure Limit</li> <li>Needle Safety and Reliability</li> <li>Needle Use</li> <li>Needle Tip Access</li> </ul> |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
| <b>Test(s)</b>                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>Needle Point Exposure Limit</li> <li>Needle Safety and Reliability</li> <li>Needle Use</li> <li>Needle Tip Access</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
|                                                                                                                                                                                                                              | <table> <tr> <td colspan="2"><b>Reference Standard: ISO 7864:2016 Sterile Hypodermic Needles for Single Use – Requirements and Test Methods</b></td></tr> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>Needle Cleanliness</li> <li>Needle Hub Socket Cleanliness</li> <li>Needle Point</li> </ul> </td></tr> <tr> <td colspan="2"><b>Reference Standard: ISO 80369-1:2018 and -7:2021 Small-bore Connectors for Liquids and Gases in Healthcare Applications Part 1: General Requirements, Part 7: Connectors for Intravascular or Hypodermic Applications</b></td></tr> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>Dimensions</li> <li>ISO Luer Functional Performance</li> </ul> </td></tr> <tr> <td colspan="2"><b>Reference Standard: ISO 9626:2016 Stainless Steel Needle Tubing for the Manufacture of Medical Devices – Requirements and Test Methods</b></td></tr> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>Needle Cleanliness</li> <li>Needle Surface</li> <li>Needle Stiffness</li> <li>Needle Breakage</li> </ul> </td></tr> <tr> <td colspan="2"><b>Reference Standard: USP &lt;788&gt;:2012 Small Volume Injections – Particulate Matter in Injections</b></td></tr> <tr> <td><b>Test(s)</b></td><td> <ul style="list-style-type: none"> <li>Particulate</li> </ul> </td></tr> </table> | <b>Reference Standard: ISO 7864:2016 Sterile Hypodermic Needles for Single Use – Requirements and Test Methods</b> |                                                                                                                                                                     | <b>Test(s)</b> | <ul style="list-style-type: none"> <li>Needle Cleanliness</li> <li>Needle Hub Socket Cleanliness</li> <li>Needle Point</li> </ul> | <b>Reference Standard: ISO 80369-1:2018 and -7:2021 Small-bore Connectors for Liquids and Gases in Healthcare Applications Part 1: General Requirements, Part 7: Connectors for Intravascular or Hypodermic Applications</b> |  | <b>Test(s)</b> | <ul style="list-style-type: none"> <li>Dimensions</li> <li>ISO Luer Functional Performance</li> </ul> | <b>Reference Standard: ISO 9626:2016 Stainless Steel Needle Tubing for the Manufacture of Medical Devices – Requirements and Test Methods</b> |  | <b>Test(s)</b> | <ul style="list-style-type: none"> <li>Needle Cleanliness</li> <li>Needle Surface</li> <li>Needle Stiffness</li> <li>Needle Breakage</li> </ul> | <b>Reference Standard: USP &lt;788&gt;:2012 Small Volume Injections – Particulate Matter in Injections</b> |  | <b>Test(s)</b> | <ul style="list-style-type: none"> <li>Particulate</li> </ul> |
| <b>Reference Standard: ISO 7864:2016 Sterile Hypodermic Needles for Single Use – Requirements and Test Methods</b>                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
| <b>Test(s)</b>                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>Needle Cleanliness</li> <li>Needle Hub Socket Cleanliness</li> <li>Needle Point</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
| <b>Reference Standard: ISO 80369-1:2018 and -7:2021 Small-bore Connectors for Liquids and Gases in Healthcare Applications Part 1: General Requirements, Part 7: Connectors for Intravascular or Hypodermic Applications</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
| <b>Test(s)</b>                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>Dimensions</li> <li>ISO Luer Functional Performance</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
| <b>Reference Standard: ISO 9626:2016 Stainless Steel Needle Tubing for the Manufacture of Medical Devices – Requirements and Test Methods</b>                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
| <b>Test(s)</b>                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>Needle Cleanliness</li> <li>Needle Surface</li> <li>Needle Stiffness</li> <li>Needle Breakage</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
| <b>Reference Standard: USP &lt;788&gt;:2012 Small Volume Injections – Particulate Matter in Injections</b>                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
| <b>Test(s)</b>                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>Particulate</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
| <b>Technological Comparison to Predicate Device</b>                                                                                                                                                                          | <p>Technological characteristics of the subject CentroVena Central Venous Catheter (CVC) with the CentroVena One Insertion System are substantially equivalent with regard to the intended use and basic design and function of the predicate device, BD Acute Central Line (K190855). The tip geometry, materials, labeling and packaging modifications and the addition of an insertion system device differ from the predicate device. The inclusion of the CentroVena One Insertion System has no impact on the substantial equivalence as it is comprised of several of the same components used in the predicate device kits. Therefore, these differences do not alter the intended use of the subject device, and do not raise any new or different questions regarding safety or effectiveness when compared to the predicate device.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |
| <b>Summary of Substantial Equivalence</b>                                                                                                                                                                                    | <p>Based on the risk management activities and testing, the subject device, CentroVena Central Venous Catheter (CVC) with the CentroVena One Insertion System, has been demonstrated to be substantially equivalent to the cited predicate device.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                    |                                                                                                                                                                     |                |                                                                                                                                   |                                                                                                                                                                                                                              |  |                |                                                                                                       |                                                                                                                                               |  |                |                                                                                                                                                 |                                                                                                            |  |                |                                                               |