March 10, 2017

Becton Dickinson Infusion Therapy Systems, Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street North West
Buffalo, Minnesota 55313

Re: K170336
Trade/Device Name:  BD Nexiva™ Closed IV Catheter System-Single Port with MaxZero™ Needleless Connector
Regulation Number:  21 CFR 880.5200
Regulation Name:  Intravascular Catheter
Regulatory Class:  Class II
Product Code:  FOZ, FPA
Dated:  March 7, 2017
Received:  March 8, 2017

Dear Mr. Mark Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Device Name
BD Nexiva Closed IV Catheter System - Single Port with MaxZero Needleless Connector

Indications for Use

BD Nexiva Closed IV Catheter System - Single Port with MaxZero Needleless Connector devices are intended to be inserted into a patient’s vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. The 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.

Type of Use (Select one or both, as applicable)

☑️ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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### Submitter Information
- **Submitter Name:** Becton Dickinson Infusion Therapy Systems Inc.
- **Submitter Address:** 9450 South State Street, Sandy, UT 84070
- **Contact Person:** Kimberly Geisler, Regulatory Affairs Manager
- **Email Address:** kimberly.geisler@bd.com
- **Phone Number:** (801) 565-2422
- **Fax Number:** (801) 304-3963
- **Date of Preparation:** March 3, 2017

### Subject Device
- **Trade Name:** BD Nexiva™ Closed IV Catheter System – Single Port with MaxZero™ Needleless Connector
- **Common Name:** Peripheral Intravascular or IV Catheter
- **Regulation Number:** 21 CFR §880.5200
- **Regulation Name:** Intravascular Catheter
- **Regulatory Class:** II
- **Product Code:** FOZ (primary); FPA (secondary)
- **Classification Panel:** General Hospital

### Predicate Device (BD Nexiva)
- **Trade Name:** BD Nexiva™ Closed IV Catheter System – Single Port
- **510(k) Reference:** K161777
- **Common Name:** Peripheral Intravascular or IV Catheter
- **Regulation Number:** 21 CFR §880.5200
- **Regulation Name:** Intravascular Catheter
- **Regulatory Class:** II
- **Product Code:** FOZ
- **Classification Panel:** General Hospital

### Predicate Device (MaxZero)
- **Trade Name:** MaxZero™ Needleless Connector (MZ1000)
- **510(k) Reference:** K132413
- **Common Name:** Intravascular Administration Set or Needleless Connector
- **Regulation Number:** 21 CFR §880.5440
- **Regulation Name:** Intravascular Administration Set
- **Regulatory Class:** II
- **Product Code:** FPA
- **Classification Panel:** General Hospital

### Reason for Submission
The reason for this submission is the addition of a MaxZero Needleless Connector to the BD Nexiva Closed IV Catheter System – Single Port unit package.
Device Description
BD Nexiva Closed IV Catheter System – Single Port with MaxZero Needleless Connector devices are over-the-needle, intravascular catheters. These devices have a radiopaque BD Vialon catheter, needle, needle shield, septum, stabilization platform, integrated extension tubing, clamp, Luer adapter, and vent plug. The needle and catheter are protected by a needle cover. A MaxZero device with protective cover is provided in the unit package.

The closed system is designed to keep blood contained within the device throughout the insertion process. The septum is designed to wipe visible blood from the needle surface as the needle is withdrawn from the catheter, further reducing the risk of blood exposure. The needle tip is passively protected when the needle is removed, reducing the risk of accidental needlestick injury.

These devices have BD Instaflash needle technology, allowing for immediate visualization of blood return along the catheter. Continuous blood return is seen in the extension tubing. The vent plug prevents blood leakage from the extension tubing during insertion. Both the stabilization platform and Luer connector are color coded to indicate catheter gauge size (24 GA (0.7 mm)=Yellow, 22 GA (0.9 mm)=Blue, 20 GA (1.1 mm)=Pink, 18 GA (1.3 mm)=Green).

Indications for Use
The subject device Indications for Use is the same as the predicate BD Nexiva Closed IV Catheter System – Single Port device (K16177), with the exception of the device trade name. The subject device Indications for Use does not include the predicate MaxZero Needleless Connector Indications for Use (K132413) since the MaxZero Needleless Connector is a component of the primary BD Nexiva Closed IV Catheter System – Single Port device. The addition of the MaxZero Needleless Connector to the BD Nexiva Closed IV Catheter System unit package does not impact the intended use of the MaxZero Needleless Connector compared to the predicate device (K132413). As such, the differences between the subject and predicate device Indications for Use do not change the intended use of the predicate devices or raise different questions of safety and effectiveness.

### SUBJECT
**BD Nexiva Closed IV Catheter System – Single Port with MaxZero Needleless Connector**
*Indications for Use*
BD Nexiva Closed IV Catheter System – Single Port with MaxZero Needleless Connector devices are intended to be inserted into a patient’s vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. The 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.

### PREDICATE 1
**BD Nexiva Closed IV Catheter System – Single Port (K16177)**
*Indications for Use*
BD Nexiva closed IV catheter systems are intended to be inserted into a patient’s vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. The 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.

### PREDICATE 2
**MaxZero Needleless Connector (K132413)**
*Indications for Use*
The MaxZero Needleless Connector is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. The MaxZero Needleless Connector can be used for direct injection, intermittent infusion, continuous infusion or aspiration.
Technological Characteristics

Technological characteristics of the subject and predicate devices are substantially equivalent with respect to the device design and materials. The subject BD Nexiva Closed IV Catheter System - Single Port with MaxZero Needleless Connector achieves its intended use based on the same technology and principles of operation as the predicate BD Nexiva Closed IV Cather System - Single Port and MaxZero Needleless Connector, respectively.

The BD Nexiva Closed IV Catheter System - Single Port is being offered with a MaxZero Needleless Connector in the unit package as a convenience to the clinician. This configuration represents a change the MaxZero sterilization method from irradiation (e-beam) to ethylene oxide (EtO).

A comparison of the subject and predicate device technological characteristics is provided in the table below.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>SUBJECT BD Nexiva Closed IV Catheter System – Single Port with MaxZero Needleless Connector</th>
<th>PREDICATE 1 BD Nexiva Closed IV Catheter System – Single Port (K161777)</th>
<th>PREDICATE 2 MaxZero Needleless Connector (K132413)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Owner</td>
<td>Becton Dickinson Infusion Therapy Systems Inc.</td>
<td>Becton Dickinson Infusion Therapy Systems Inc.</td>
<td>Becton, Dickinson and Company (formerly CareFusion)</td>
</tr>
<tr>
<td>Classification</td>
<td>21 CFR §880.5200 Class II FOZ - Intravascular Catheter (primary)</td>
<td>21 CFR §880.5200 Class II FOZ - Intravascular Catheter</td>
<td>21 CFR §880.5440 Class II FPA - IV Administration Set</td>
</tr>
<tr>
<td>510(k) Status</td>
<td>Subject of this premarket notification</td>
<td>K161777 – Clearance date August 29, 2016</td>
<td>K132413 – Clearance date August 29, 2013</td>
</tr>
<tr>
<td>Fundamental Scientific Technology</td>
<td><strong>BD Nexiva Closed IV Catheter System – Single Port device</strong> Same as Predicate 1 (BD Nexiva SP)</td>
<td><strong>MaxZero Needleless Connector device</strong> Same as Predicate 2 (MaxZero)</td>
<td><strong>Closed peripheral intravascular catheter system designed with an integrated extension set incorporating a single port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization.</strong> Closed, Luer activated needleless connector designed to prevent fluid displacement into the catheter upon disconnection of the male user (i.e., zero reflux). During activation, a male Luer lock connector causes the valve to deflect and enables fluid to flow freely around the valve and out the male Luer connector.</td>
</tr>
<tr>
<td>Primary Device Components / Materials</td>
<td><strong>BD Nexiva Closed IV Catheter System – Single Port device</strong> Same as Predicate 1 (BD Nexiva Closed IV Catheter System – Single Port)</td>
<td><strong>MaxZero Needleless Connector device</strong> Same as Predicate 2 (MaxZero Needleless Connector)</td>
<td><strong>Needle:</strong> Stainless Steel <strong>Catheter:</strong> Polyurethane <strong>Catheter Wings:</strong> TPE <strong>Catheter Adapter:</strong> Copolyester <strong>Needle Hub:</strong> Polycarbonate <strong>Tip Shield:</strong> Polycarbonate <strong>Extension Tubing:</strong> Polyurethane <strong>Luer Adapter:</strong> Copolyester <strong>Pinch Clamp:</strong> Acetal <strong>Top:</strong> Polycarbonate <strong>Base:</strong> Polycarbonate <strong>Valve:</strong> Silicone</td>
</tr>
</tbody>
</table>
Summary of Performance Tests

Performance tests completed on the subject device were limited to those tests required to support a determination of substantial equivalence to the predicate devices. A risk analysis was conducted to assess the impact of the proposed modifications to the subject devices. When technological characteristics between the subject and predicate devices were found to be identical, results of performance testing conducted on the predicate devices were applied to the subject device. The performance tests listed below were identified to ensure that specified design requirements were met:

- MaxZero Insertion Force
- MaxZero Droplet Size
- MaxZero High Back Pressure
- MaxZero Droplet Separation
- MaxZero Flow Rate
- BD Nexiva Flow Control Plug Retention Rate
- Packaging Integrity
- Damage to Device

In addition, the following biocompatibility testing was conducted on the MaxZero Needleless Connector as a result of the sterilization method change in accordance with ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity (Acute)
- Haemocompatibility
- Pyrogenicity (Material-Mediated Rabbit Pyrogen)
- Pyrogenicity (LAL)

Per the design control requirements specified in 21 CFR §820.30, the subject device met all predetermined acceptance criteria for the above-listed performance tests, demonstrating substantial equivalence to the predicate devices.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and results of performance testing, the subject BD Nexiva Closed IV Catheter System (Single Port) with MaxZero Needleless Connector has been demonstrated to be substantially equivalent to the predicate devices.