DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 29, 2016

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

Re: K161777
Trade/Device Name: BD Nexiva™ and BD Nexiva™ Diffusics™ Closed IV Catheter Systems
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II,
Product Code: FOZ
Dated: August 12, 2016
Received: August 16, 2016

Dear Mr. 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" (21CFR 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,

Michael J. Ryan -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
BD Nexiva Closed IV Catheter System

Indications for Use *(Describe)*

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 22-18GA (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.

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:

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
BD Nexiva Diffusics Closed IV Catheter System

Indications for Use *(Describe)*

BD Nexiva Diffusics 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 devices 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. These devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 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)

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510(k) Summary (21 CFR §807.92)

BD Nexiva™ and BD Nexiva™ Diffusics™ Closed IV Catheter Systems

Submitter Information	Submitter Name: Submitter Address:	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, UT 84070
	Contact Person:	Kimberly Geisler Staff Regulatory Affairs Specialist kimberly.geisler@bd.com (801) 565-2422 (phone)
	Date of Preparation:	July 28, 2016
Subject Device ***(BD Nexiva)***	Trade Name: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Nexiva™ Closed IV Catheter System Peripheral Intravascular or IV Catheter 21 CFR §880.5200 Intravascular Catheter II FOZ General Hospital
Predicate Device ***(BD Nexiva)***	Trade Name: 510(k) Reference: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Nexiva™ Closed IV Catheter System K102520 Peripheral Intravascular or IV Catheter 21 CFR §880.5200 Intravascular Catheter II FOZ General Hospital
Subject Device ***(BD Nexiva Diffusics)***	Trade Name: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Nexiva™ Diffusics™ Closed IV Catheter System Peripheral Intravascular or IV Catheter 21 CFR §880.5200 Intravascular Catheter II FOZ General Hospital
Predicate Device ***(BD Nexiva Diffusics)***	Trade Name: 510(k) Reference: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Nexiva™ Diffusics™ Closed IV Catheter System K123734 Peripheral Intravascular or IV Catheter 21 CFR §880.5200 Intravascular Catheter II FOZ General Hospital

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Device Description ***(BD Nexiva)***	BD Nexiva closed IV catheter systems 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, vent plug and, with dual port configurations, a pre-attached BD Q-Syte Luer Access Split Septum. The needle and catheter are protected by a needle cover. For dual port configurations, a BD Q-Syte device or an end cap 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 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 (24GA (0.7 mm)=Yellow, 22GA (0.9 mm)=Blue, 20GA (1.1 mm)=Pink, 18GA (1.3 mm)=Green).
Device Description ***(BD Nexiva Diffusics)***	BD Nexiva Diffusics closed IV catheter systems are over-the-needle, intravascular catheters. These devices have a radiopaque BD Vialon™ catheter with side holes located near the tip of the catheter which are designed to optimize power injection procedures. These devices also have a needle, needle shield, septum, stabilization platform, integrated extension tubing, clamp, Luer connector, and vent plug. The Luer connector displays gauge-specific maximum flow rate and the maximum power injector pressure limit setting. The needle and catheter are protected by a needle cover. An end cap 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 along the catheter. Continuous blood return is seen in the extension tubing. The vent plug prevents blood leakage from the extension tubing during insertion. The stabilization platform and Luer connector are color coded to indicate catheter gauge size (24GA (0.7 mm)=Yellow, 22GA (0.9 mm)=Blue, 20GA (1.1 mm)=Pink, 18GA (1.3 mm)=Green).

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Indications for Use
(BD Nexiva)

Modifications were made to the Indications for Use for the purpose of aligning the Indications for Use across the BD Nexiva family of products and for clarification.

Modifications include: 1) removal of the regulation reference as it is not relevant to the healthcare practitioner; 2) removal of device features and performance information which does not determine intended use; 3) removal of "less than 30 days" since this statutory regulation language for 21 CFR §880.5200 regarding the device classification could be confusing to end users as the duration of use is dependent on a number of factors, including patient status, duration of treatment, and institutional protocol; 4) addition of "fluids being infused" and "duration of therapy" as considerations for clinicians to evaluate prior to use of these catheters for a particular patient; and 5) minor wording changes.

None of these changes are critical to the intended use and do not raise new questions of safety and effectiveness of the devices when used as indicated.

SUBJECT **BD Nexiva™ Closed IV Catheter System** ***Indications for Use***	**PREDICATE (K102520)** **BD Nexiva™ Closed IV Catheter System** ***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 22-18GA (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.	As indicated in 21 CFR Part 880.5200, The Nexiva™ intravascular catheter is inserted into a patient's vascular system for a short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravascularly. The needle-shielding feature and luer access port, aid in the prevention of needle-stick injuries. Blood is contained within the device during the catheter insertion process aiding in the prevention of blood exposure. This catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure. The 18-22 gauge Nexiva™ catheters are suitable for use with power injectors rated for a maximum of 300 psi when the luer access port(s) is removed and a direct connection is made.

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Indications for Use
(BD Nexiva Diffusics)

Modifications were made to the Indications for Use for the purpose of aligning the Indications for Use across the BD Nexiva family of products and for clarification.

Modifications include: 1) addition of "short term use" in alignment with the device classification; 2) addition of the intended patient population, which is consistent with the predicate device, which does not indicate a specific patient population and is intended for general use; 3) removal of the flow rate information as it pertains to device performance and does not determine intended use (*Note*: flow rate information is provided in the Instructions for Use); and 4) minor wording changes. None of these changes are critical to the intended use and do not raise new questions of safety and effectiveness of the devices when used as indicated.

SUBJECT **BD Nexiva™ Diffusics™ Closed IV Catheter System** ***Indications for Use***	**PREDICATE (K123734)** **BD Nexiva™ Diffusics™ Closed IV Catheter System** ***Indications for Use***
BD Nexiva Diffusics 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 devices 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. These devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa) when access ports not suitable for use with power injectors are removed.	The BD Nexiva™ Diffusics™ intravascular catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure or administer fluids. The BD Nexiva Diffusics catheters are suitable for use with power injectors when a direct connection is made. The maximum flow rate and maximum power injector pressure setting for each catheter size are listed in the table below:

	Max Flow Rate (mL/sec)	Max Injector Setting (psi)
24 GA x 0.75 IN	3.0	325
22 GA x 1.00 IN	6.5	325
20 GA x 1.00 IN	10.0	325
20 GA x 1.25 IN	10.0	325
18 GA x 1.25 IN	15.0	325

Technological Characteristics

Technological characteristics of the subject and predicate devices are equivalent. The subject BD Nexiva™ and BD Nexiva™ Diffusics™ Closed IV Catheter Systems achieve their intended use based on the same technology and principles of operation as the predicate BD Nexiva™ and BD Nexiva™ Diffusics™ Closed IV Cather Systems, respectively. Design modifications were made to the subject devices to reduce the force required to withdraw the needle from the catheter assembly. Performance testing performed to support the design modifications included:

- Air Leakage
- Liquid Leakage
- Fluid Leakage at Venous Pressure
- Septum Assembly Failure / Separation at Max Pressure
- Cannula / Hub Bond Strength
- Strength of Union between Needle Hub and Needle Tube
- Force to Remove Needle from Catheter System (Average System Drag)
- System Drag – Peak Offset Force

All of the pre-determined acceptance criteria were met.

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Attribute	SUBJECT BD Nexiva™ Closed IV Catheter System	PREDICATE (K102520) BD Nexiva™ Closed IV Catheter System
Classification	Same as predicate	21 CFR §880.5200 Class II FOZ - Intravascular Catheter
Fundamental Scientific Technology	Same as predicate	Closed peripheral intravascular catheter system designed with an integrated extension set incorporating either a single port or Y (dual)-port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization.
Components / Materials	Septum Canister: Copolyester + **grey colorant***	Septum Canister: Copolyester + **white colorant**
	All other subject component materials are the same as the predicate device	
Physical / Mechanical Specifications	Same as predicate	Catheter Diameters: 18G, 20G, 22G, 24G Catheter Lengths: 0.56”, 0.75”, 1.00”, 1.25”, 1.75”

*The subject BD Nexiva™ Closed IV Catheter System and subject BD Nexiva™ Diffusics™ Closed IV Catheter System septum canister materials are identical. As such, the Nexiva™ Diffusics™ Closed IV Catheter System (K123734) serves as the reference device supporting this modification to the BD Nexiva™ Closed IV Catheter System non-patient contacting septum canister material.

Attribute	SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System	PREDICATE (K123734) BD Nexiva™ Diffusics™ Closed IV Catheter System
Classification	Same as predicate	21 CFR §880.5200 Class II FOZ - Intravascular Catheter
Fundamental Scientific Technology	Same as predicate	Closed peripheral intravascular catheter system designed with an integrated extension set incorporating either a single port or Y (dual)-port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization. In addition, the catheter tip includes diffuser holes to reduce the velocity of contrast media exiting the catheter tip during CT scans.
Components / Materials	Septum Canister: Copolyester + grey colorant **(modified resin to colorant ratio compared to predicate)**	Septum Canister: Copolyester + grey colorant
	Septum: Polyisoprene **(no lubricant)**	Septum: Polyisoprene + Silicone Lubricant
	All other subject component materials are the same as the predicate device	
Physical / Mechanical Specifications	Same as predicate	Catheter Diameters: 18G, 20G, 22G, 24G Catheter Lengths: 0.75”, 1.00”, 1.25”

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Summary of Performance Tests	The following performance testing was performed to demonstrate substantial equivalence of the subject BD Nexiva™ and BD Nexiva™ Diffusics™ Closed IV Catheter Systems to the predicate BD Nexiva™ Closed IV Catheter System (K102520) and BD Nexiva™ Diffusics™ Closed IV Catheter System (K123734), respectively, and applicable standards: • Air Leakage • Liquid Leakage • Fluid Leakage at Venous Pressure • Septum Assembly Failure / Separation at Max Pressure • Cannula / Hub Bond Strength • Strength of Union between Needle Hub and Needle Tube • Force to Remove Needle from Catheter System (Average System Drag) • System Drag – Peak Offset Force All of the pre-determined acceptance criteria were met.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and performance testing, the subject BD Nexiva™ Closed IV Catheter System and BD Nexiva™ Diffusics™ Closed IV Catheter System are demonstrated to be substantially equivalent to the predicate BD Nexiva™ Closed IV Catheter System (K102520) and BD Nexiva™ Diffusics™ Closed IV Catheter System (K123734), respectively.