DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 28, 2017

Becton, Dickinson and Company
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street North West
Buffalo, Minnesota 55313

Re: K170283
Trade/Device Name: BD Nexiva™ Diffusics™ Closed IV Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: January 13, 2017
Received: January 30, 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

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)*
K170283

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K170283

510(k) Summary (21 CFR §807.92)

BD Nexiva™ Diffusics™ Closed IV Catheter System

Submitter Information	Submitter Name: Submitter Address:	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, UT 84070
	Contact Person: Email Address: Phone Number: Fax Number Date of Preparation:	Amy Honey Regulatory Affairs Specialist amy.honey@bd.com (801) 304-3908 (801) 304-3963 January 13, 2017
Subject Device	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	Trade Name: 510(k) Reference: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Nexiva™ Diffusics™ Closed IV Catheter System K161777 Peripheral Intravascular or IV Catheter 21 CFR §880.5200 Intravascular Catheter II FOZ General Hospital
Device Description	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 (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	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.
Technological Characteristics	Technological characteristics of the subject and predicate devices are substantially equivalent with respect to the basic design and materials, and the subject BD Nexiva™ Diffusics™ Closed IV Catheter System achieves its intended use based on the same technology and principles of operation as the predicate BD Nexiva™ Diffusics™ Closed IV Cather System. Design modifications have been made to the subject device Luer adapter internal geometry to move the extension tubing / Luer adapter bond location away from the extension tubing bend point. Performance testing conducted to support the design modification are as follows: • No Leak after Repeated Bending Cycles • Luer Adapter Pull Force All pre-determined acceptance criteria were met. A comparison of the subject and predicate device technological characteristics is provided in the table below.

Attribute	SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System	PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System (K161777)
Classification	Same as predicate	21 CFR §880.5200 Class II FOZ - Intravascular Catheter
Indications for Use	Same as predicate	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.
Fundamental Scientific	Same as predicate	Closed peripheral intravascular catheter systems are designed with an integrated extension set incorporating

Attribute	SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System	PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System (K161777)
Technology		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.
Primary Device Materials	Same as predicate	Needle: Stainless Steel Catheter: Polyurethane Catheter Wings: TPE Catheter Adapter: Copolyester Needle Hub: Polycarbonate Tip Shield: Polycarbonate Extension Tubing: Polyurethane Luer Adapter: Copolyester Pinch Clamp: Acetal
Physical / Mechanical Specifications	Same as predicate	Catheter Diameters: 18G, 20G, 22G, 24G Catheter Lengths: 0.75”, 1.00”, 1.25”
Sterility	Same as predicate	Provided sterile (EO)

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 device. A risk analysis was conducted to assess the impact of the proposed modifications to the subject device, and the performance tests listed below were identified to ensure that specified design requirements were met:

- No Leak after Repeated Bending Cycles
- Luer Adapter Pull Force

When technological characteristics between the subject and predicate device were found to be identical, results of performance testing conducted on the predicate device were applied to the subject device.

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 device.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and results of performance testing, the subject BD Nexiva™ Diffusics™ Closed IV Catheter System has been demonstrated to be substantially equivalent to the predicate device.