March 6, 2018

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

Re: K173354
Trade/Device Name: BD Nexiva Diffusics Closed IV Catheter Systems
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: October 23, 2017
Received: October 25, 2017

Dear Mark Job:

This letter corrects our substantially equivalent letter of December 15, 2017.

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 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173354

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.

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

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K173354

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:	Henry Boland Staff Regulatory Affairs Specialist henry.boland@bd.com (801) 565-2550
	Date of Preparation:	November 17, 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 K170283 Peripheral Intravascular or IV Catheter 21 CFR §880.5200 Intravascular Catheter II FOZ General Hospital
Reason for Submission	The reason for this submission is to notify CDRH of a modification to the BD Nexiva™ Diffusics™ Closed IV Catheter System. The modification is a change to extension tubing polyurethane material formulation and manufacturer.	
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

(21 CFR §807.92(a)(5))

The subject device Indications for Use is the same as the predicate BD Nexiva™ Diffusics™ Closed IV Catheter System (K170283).

SUBJECT DEVICE	PREDICATE DEVICE (K170283)
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.	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 device are substantially equivalent to the predicate device. 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. The subject device has been modified from the predicate device as listed below. The results of design verification demonstrate that these changes are substantially equivalent to the predicate device. All other aspects of the subject device are identical to those of the predicate device.

- Change to Extension Tubing polyurethane material formulation and manufacturer

Attribute	SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System	PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System (K170283)
Design	A winged, power injectable, polyurethane IV catheter with an integrated extension set incorporating either a single port or Y (dual)-port injection site. Incorporates BD Instaflash™ technology to assist with	A winged, power injectable, polyurethane IV catheter with an integrated extension set incorporating either a single port or Y (dual)-port injection site. Incorporates BD Instaflash™ technology to assist with

Attribute	SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System	PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System (K170283)
	flashback visualization.	flashback visualization.

Materials	Component	SUBJECT DEVICE	PREDICATE DEVICE (K170283)
	Needle Cover	LDPE	LDPE
	Needle	Stainless Steel	Stainless Steel
	Needle Adhesive	Acrylated Urethane	Acrylated Urethane
	Needle Lubricant	Silicone	Silicone
	Catheter Tubing	BD Vialon™ Polyurethane with Barium Sulfate	BD Vialon™ Polyurethane with Barium Sulfate
	Catheter Lubricant	Silicone	Silicone
	Catheter Tipping Lubricant	Silicone	Silicone
	Catheter Adapter Wings	TPE with gauge-specific colorant	TPE with gauge-specific colorant
	Catheter Adapter	Copolyester	Copolyester
	Wedge	Stainless steel	Stainless steel
	Septum Canister	Copolyester with grey colorant	Copolyester with grey colorant
	Septum	Polyisoprene	Polyisoprene
	V-Clip	Stainless steel with parylene coating	Stainless steel with parylene coating
	Retention Washer	Stainless steel	Stainless steel
	Tip Shield	Polycarbonate with grey colorant	Polycarbonate with grey colorant
	Grip/Needle Hub	Polycarbonate with white colorant	Polycarbonate with white colorant
	Pinch Clamp	Acetal with blue colorant	Acetal with blue colorant
	Extension Tubing	**Polyurethane**	Polyurethane
	Extension Tubing Adhesive	Acrylic	Acrylic
	Luer Adapter	Copolyester with gauge - specific colorant White print ink	Copolyester with gauge - specific colorant White print ink
	Luer Adapter Overmold	TPE with blue colorant	TPE with blue colorant
	End Cap	Polypropylene with white colorant	Polypropylene with white colorant
	End Cap Protective Cover	HDPE with blue colorant	HDPE with blue colorant
	Vent Plug	Polypropylene and acrylic-nylon membrane	Polypropylene and acrylic-nylon membrane

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 conducted to ensure that specified design requirements were met: • No Leak after Repeated Bending Cycles • Extension Set Pull Force • Extension Tube Yield / Rupture Pressure • Pinch Clamp Vacuum Occlusion • Pinch Clamp Engagement Force In addition, the following biocompatibility testing was conducted 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) • Material-Mediated Pyrogenicity • Subchronic Toxicity (subacute toxicity) • Haemocompatibility Finally, particulate analysis of the surface and fluid path was conducted, upon the guidance of USP <788>, as clinically relevant. 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 performance testing, the subject BD Nexiva™ Diffusics™ Closed IV Catheter System meets the same pre-determined requirements as the predicate device, which BD developed as required by 21 CFR 820.30 Design Controls. The testing confirms that the subject device is substantially equivalent to the predicate BD Nexiva™ Diffusics™ Closed IV Catheter System.