November 30, 2018

Becton, Dickinson and Company
Amy Honey
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K181221
Trade/Device Name: BD PhaSeal Optima Closed System Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: October 22, 2018
Received: October 24, 2018

Dear Amy Honey:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; 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 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,

Alan M. Stevens -S

for 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)*
K181221

Device Name
BD PhaSeal Optima Closed System Transfer Device

Indications for Use *(Describe)*
The BD PhaSeal™ Optima system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The BD PhaSeal™ Optima system also prevents microbial ingress for up to 168 hours.

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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K181221

510(k) Summary (21 CFR §807.92)

BD PhaSeal™ Optima Closed System Transfer Device

Submitter Information	Submitter Name: Submitter Address: Contact Person: Email Address: Phone Number: Fax Number: Date of Preparation:	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 Amy Honey Staff Regulatory Affairs Specialist amy.honey@bd.com Phone: (801) 304-3908 Fax: (801) 304-3963 November 30, 2018
Subject Device	Trade Name: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD PhaSeal™ Optima Closed System Transfer Device Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System 21 CFR §880.5440 Intravascular Administration Set II ONB General Hospital
Predicate Device	Trade Name: 510(k) Reference: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD PhaSeal™ Closed System Transfer Device K123213 Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System 21 CFR §880.5440 Intravascular Administration Set II ONB General Hospital
Device Description	The BD PhaSeal™ Optima Closed System Transfer Device (CSTD) is a sterile single-use closed system drug transfer device intended for the reconstitution and transfer of antineoplastic or other hazardous drugs in the healthcare setting. The system is comprised of four devices—Protector, Injector, Connector, and Infusion Adapter. The closed transfer of liquid drugs takes place through a double membrane utilizing self-sealing elastomeric membranes that are tightly fitted together through the collet-style fitting on each of the BD PhaSeal™ Optima system devices. During use, the single lumen cannula of the Injector perforates the double membranes for the transfer of liquids. When the cannula is retracted the membranes seal off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing the individual and environmental exposure to drug vapor, aerosols, leaks and spills. The BD PhaSeal™ Optima system prevents microbial ingress for up to 168 hours. Performance of the self-sealing membrane has been substantiated up to 10 penetrations.	

Indications for Use	The BD PhaSeal™ Optima system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The BD PhaSeal™ Optima system also prevents microbial ingress for up to 168 hours.
Technological Characteristics	Technological characteristics of the subject BD PhaSeal™ Optima Closed System Transfer Device (CSTD) are substantially equivalent to that of the predicate BD PhaSeal™ Closed System Transfer Device (CSTD) with respect to basic design and function. The subject BD PhaSeal™ Optima Closed System Transfer Device (CSTD) achieves its intended use based on the same technology and principles of operation as the predicate BD PhaSeal™ Closed System Transfer Device (CSTD). The key differences between the subject and predicate device are as follows: • The action to connect mating devices within the subject BD PhaSeal™ Optima CSTD system is a push on-pull off motion rather than the push-turn-push motion of the predicate BD PhaSeal™ CSTD device. • The connection between the subject BD PhaSeal™ Optima CSTD system devices (Injector to Protector, Connector, or Infusion Adapter) is a collet-style fitting with elastomeric double membranes rather than the bayonet fitting with elastomeric double membranes of the predicate BD PhaSeal™ CSTD device. • The Injector needle mechanism of the subject BD PhaSeal™ Optima CSTD device is a collet-style fitting rather than the Safety Sleeve ErgoMotion™ of the predicate BD PhaSeal™ CSTD device. A comparison of the subject and predicate device technological characteristics is provided in the table below.

Subject and Predicate Device Comparison Table		
Attribute	**SUBJECT BD PhaSeal™ Optima Closed System Transfer Device**	**PREDICATE BD PhaSeal™ Closed System Transfer Device (K123213)**
Indications for Use	The BD PhaSeal™ Optima system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The BD PhaSeal™ Optima system also prevents microbial ingress for up to 168 hours.	The PhaSeal™ system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal™ system also prevents microbial ingress.
Devices of the CSTD System	Protector, Injector, Connector, Infusion Adapter	Protector, Injector, Connector, Infusion Adapter

Subject and Predicate Device Comparison Table (cont.)		
Attribute	**SUBJECT** **BD PhaSeal™ Optima Closed System Transfer Device**	**PREDICATE** **BD PhaSeal™ Closed System Transfer Device (K123213)**
Primary Device Materials	Membrane (all devices) Polyisoprene Cannula (Injector) Stainless Steel Injector Lube Silicone Needle Hub (Injector) Polypropylene Spike (Protector) Polypropylene Spike Sleeve (Protector) Thermoplastic Elastomer (TPE) Connector Body Polypropylene Infusion Spike (Infusion Adapter) Polypropylene Infusion Port (Infusion Adapter) Thermoplastic Elastomer (TPE)	Membrane (all devices) Thermoplastic Elastomer (TPE) Cannula (Injector) Stainless Steel Injector Lube N/A Needle Hub (Injector Polypropylene Spike or Cannula (Protector) Polypropylene or Stainless Steel Spike Sleeve (Protector) N/A Connector Body Polypropylene Infusion Spike (Infusion Adapter) Polypropylene Infusion Port (Infusion Adapter) Thermoplastic Elastomer (TPE)
Mating Method (Action of Device Connections)	Push on-Pull off	Push-Turn-Push
Connection between Devices within the System	Collet-style fitting with elastomeric double membranes	Bayonet fitting with elastomeric double membranes
Transfer Mechanism (responsible for airtight & leak-proof connections):	Elastomeric double membrane	Elastomeric double membrane
Injector Needle Mechanism	Collet-style fitting	Safety Sleeve, ErgoMotion™
Injector Connection to Syringe	Luer Lock	Luer Lock
Connector Connection to Patient IV Line	Luer Lock connection or Spike Port	Luer Lock connection or Spike Port

Performance Tests

Performance testing was conducted to support a determination of substantial equivalence as compared to BD's own predicate device. Results of these tests demonstrate that the subject device is substantially equivalent to the predicate device. Any testing performed to a recognized standard is noted in the table below.

Performance Test	Results
Microbial ingress testing per FDA guidance document, *Intravascular Administration Sets Premarket Notification Submissions [510(k)]*	PASS
Airtight connections utilizing $TiCl_4$ vapor test	PASS
Leakproof connections testing utilizing Fluorescein test	PASS
Protector assembly force and removal force testing	PASS
Protector expansion chamber burst testing	PASS
Packaging integrity and shelf life testing per the following: ASTM D4169-16 *Standard Practice for Performance Testing of Shipping Containers and Systems* ASTM F88/F88M-15 *Standard Test Method for Seal Strength of Flexible Barrier Materials* ASTM F2096-11 *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (bubble test)*	PASS
Hazardous vapor containment using alcohol residuals level criterion	PASS
EO residuals testing per ISO 10993-7	PASS
EO sterilization validation (SAL of 10^{-6}) per ISO 11135	PASS
Pyrogenicity – bacterial endotoxin test (LAL)	PASS

In addition, a biocompatibility evaluation was conducted on the subject device per ISO 10993-1:2009, Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process. Based on the evaluation, the following biological tests were conducted:

Biocompatibility Test	Results
• Cytotoxicity per ISO 10993-5 • Sensitization per ASTM F2148 and ISO 10993-10 • Intracutaneous Reactivity per ISO 10993-10 and USP 39-NF 34 <88> • Acute Systemic Toxicity per ISO 10993-11 • Pyrogenicity (material-mediated rabbit pyrogen) per USP <151> and ISO 10993-11 • Hemolysis per ISO 10993-4	All materials are biocompatible.

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	Both the subject BD PhaSeal™ Optima Closed System Transfer Device and predicate BD PhaSeal™ Closed System Transfer Device rely on similar technology to achieve the intended use. Both devices utilize elastomeric double membranes to create the sealed environment. The main difference between the subject device and predicate device is the connection method used to attach and detach system components; however, the fundamental scientific technology used to assure an airtight and leak-proof connection remains unchanged. The results of performance and biological testing of the subject BD PhaSeal™ Optima Closed System Transfer Device met all predetermined acceptance criteria and demonstrate that the subject device is substantially equivalent to the predicate device.