August 12, 2020

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

Re: K201099
Trade/Device Name: BD PhaSeal Optima Closed System Drug Transfer Device-Injector (N40-O)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: July 9, 2020
Received: July 13, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201099

Device Name
BD PhaSeal™ Optima Closed System Drug Transfer Device – Injector (N40-O)

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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K201099

510(k) Summary (21 CFR §807.92)

BD PhaSeal™ Optima Closed System Drug Transfer Device – Injector (N40-O)

Submitter Information	Submitter Name:	Becton, Dickinson and Company
	Submitter Address:	1 Becton Drive Franklin Lakes, NJ 07417
	Contact Person:	Amy Honey Sr. Staff Regulatory Affairs Specialist
	Email Address:	amy.honey@bd.com
	Phone Number:	(801) 304-3908
	Date of Preparation:	August 11, 2020
Subject Device	Trade Name:	BD PhaSeal™ Optima Closed System Drug Transfer Device – Injector (N40-O)
	Common Name:	Closed System Drug Transfer Device (CSTD)
	Regulation Number:	21 CFR §880.5440
	Regulation Name:	Intravascular Administration Set
	Regulatory Class:	Class II
	Product Code:	ONB
	Classification Panel:	General Hospital
Predicate Device	Trade Name:	BD PhaSeal™ Optima Closed System Transfer Device
	510(k) Reference:	K181221
	Common Name:	Closed System Drug Transfer Device (CSTD)
	Regulation Number:	21 CFR §880.5440
	Regulation Name:	Intravascular Administration Set
	Regulatory Class:	Class II
	Product Code:	ONB
	Classification Panel:	General Hospital
Reason for Submission	The reason for this submission is to introduce a new product offering—the subject BD PhaSeal™ Optima Injector (N40-O)—to the BD PhaSeal™ Optima family of devices.	
Device Description	BD PhaSeal™ Optima Closed System Drug Transfer Devices (CSTD) are sterile, single use closed system drug transfer devices intended for the reconstitution and transfer of antineoplastic or other hazardous drugs in the healthcare setting. The BD	

	PhaSeal™ Optima 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. Device labeling includes the following statement: *"The ability to prevent microbial ingress for up to 7 days should not be interpreted as modifying, extending, or superseding a manufacturer's labeling recommendations for the storage and expiration dating of the drug vial. Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information."*
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 device are substantially equivalent to the predicate device. The subject BD PhaSeal™ Optima Injector N40-O achieves its intended use based on the same technology and principles of operation as the predicate device. The changes to the device include modifications to the needle hub and grip components to incorporate a ratchet mechanism that locks when rotated during clockwise rotation, and a new needle hub cover component has been added to restrict access to the needle hub. These differences were assessed in the performance tests that were carried out and there were no new questions of safety and effectiveness. In addition, there were changes to the colorants and silicone formulation used in the subject device. The colorant used in the subject device is used in different components of the predicate device; therefore, there were no new risks introduced. The silicone lube material is unchanged; therefore, there are no new biocompatibility risks introduced to the device. A comparison of the subject and predicate device technological characteristics is provided in the table below.

Attribute	SUBJECT BD PhaSeal™ Optima Closed System Transfer Device – Injector (N40-O)	PREDICATE (K181221) BD PhaSeal™ Optima Closed System Transfer Device (Injector [N35-O] device)
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	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

Attribute	SUBJECT BD PhaSeal™ Optima Closed System Transfer Device – Injector (N40-O)	PREDICATE (K181221) BD PhaSeal™ Optima Closed System Transfer Device (Injector [N35-O] device)
	and environmental exposure to drug vapor, aerosols and spills. The BD PhaSeal™ Optima system also prevents microbial ingress for up to 168 hours	environmental exposure to drug vapor, aerosols and spills. The BD PhaSeal™ Optima system also prevents microbial ingress for up to 168 hours
Devices of the CSTD System	Protector, Injector, Connector, Infusion Adapter	Protector, Injector, Connector, Infusion Adapter
Device Components/ Materials	Injector Membrane Lube Silicone Membrane Polyisoprene Injector Grip 1 Polypropylene + white colorant Injector Grip 2 Polypropylene + white colorant Needle Hub Polypropylene **+ white colorant** **Needle Hub Cover** **Polypropylene + white colorant** Cannula Stainless Steel Cannula Lube Silicone Cap Polypropylene Collet Polyoxymethylene (POM) Spring Stainless Steel	Injector Membrane Lube Silicone Membrane Polyisoprene Injector Grip 1 Polypropylene + white colorant Injector Grip 2 Polypropylene + white colorant Needle Hub Polypropylene **+ blue colorant** **N/A - does not incorporate a Needle Hub Cover** Cannula Stainless Steel Cannula Lube Silicone Cap Polypropylene Collet Polyoxymethylene (POM) Spring Stainless Steel
Mating Method (action of device connections)	Push on-Pull off	Push on-Pull off
Connection between Devices within the System	Collet style fitting with elastomeric double membranes	Collet style fitting with elastomeric double membranes
Transfer Mechanism (responsible for airtight & leak-proof connections)	Elastomeric double membrane	Elastomeric double membrane
Injector Needle Safety Mechanism	Collet style fitting	Collet style fitting

Attribute	SUBJECT BD PhaSeal™ Optima Closed System Transfer Device – Injector (N40-O)	PREDICATE (K181221) BD PhaSeal™ Optima Closed System Transfer Device (Injector [N35-O] device)
Injector Connection to External Device (e.g. syringe)	Luer Lock	Luer Lock

A risk analysis was performed for the modifications to the subject device in accordance with ISO 14971, *Medical devices – Applications of risk management to medical devices*, and possible risks were identified. Based on risk identification, verification and validation activities were carried out to ensure the risk acceptability criteria have been met and the risks have been mitigated.

Performance Tests

Per the design control requirements specified in 21 CFR 820.30, and the risks identified, the following performance tests were conducted, and all predetermined acceptance criteria were met.

Performance Test	Results
Attachment/detachment force	PASS
Fragmentation	PASS
System flow rate	PASS

Testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Summary of Substantial Equivalence

The subject device uses the same technology as the predicate device to meet its intended use of minimizing individual and environmental exposure to drug vapors, aerosols, leaks, and spills during fluid transfer when mated to other devices within the system. The indications for use, technological characteristics, and performance testing results demonstrate that the subject BD PhaSeal™ Optima Injector (N40-O) is substantially equivalent to the predicate device.