



September 12, 2025

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

Re: K250059

Trade/Device Name: BD PhaSeal™ Optima Connecting Set (C83-O); BD PhaSeal™ Optima Spike Set (C180-O)

Regulation Number: 21 CFR 880.5440

Regulation Name: Intravascular Administration Set

Regulatory Class: Class II

Product Code: ONB

Dated: August 15, 2025

Received: August 15, 2025

Dear Melissa Iwu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Wolloscheck -S

David Wolloscheck, Ph.D.

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

## Indications for Use

510(k) Number (if known)  
K250059

Device Name

BD PhaSeal™ Optima Connecting Set (C83-O) and BD PhaSeal™ Optima Spike Set (C180-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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## **K250059 - 510(k) Summary**

### **Submitter Information**

**Date Prepared:** September 12, 2025  
**Company Name:** Becton Dickinson and Company  
**Company Address:** 1 Becton Drive,  
Franklin Lakes, NJ 07417

**Establishment  
Registration Number:** 2243072  
**Name of Contact Person:** Melissa Iwu  
**Title:** Staff Regulatory Affairs Specialist  
**Email:** [melissa.iwu@bd.com](mailto:melissa.iwu@bd.com)  
**Phone:** 551.233.6635

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### **Subject Device**

**Trade Name:** BD PhaSeal™ Optima Connecting Set (C83-O);  
BD PhaSeal™ Optima Spike Set (C180-O)  
**Common Name:** Closed Antineoplastic and Drug Reconstitution and Transfer System  
**Regulation Number:** 21 CFR 880.5440  
**Regulation Name:** Intravascular Administration Set  
**Regulatory Class:** Class II  
**Product Code:** ONB  
**Classification Panel:** General Hospital  
**Manufacturer:** Becton, Dickinson and Company

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### **Predicate Device**

**Trade Name:** BD PhaSeal™ Optima Closed System Transfer Device  
**Common Name:** Closed Antineoplastic and Drug Reconstitution and Transfer System  
**Regulation Number:** 21 CFR 880.5440  
**Regulation Name:** Intravascular Administration Set  
**Regulatory Class:** Class II  
**Product Code:** ONB  
**Classification Panel:** General Hospital  
**Premarket Notification:** K181221  
**Manufacturer:** Becton, Dickinson and Company

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### **Reference Device**

**Trade Name:** BD PhaSeal™ Optima Injector (N40-O)  
**Common Name:** Closed Antineoplastic and Drug Reconstitution and Transfer System  
**Regulation Number:** 21 CFR 880.5440  
**Regulation Name:** Intravascular Administration Set  
**Regulatory Class:** Class II  
**Product Code:** ONB  
**Classification Panel:** General Hospital  
**Premarket Notification:** K201099  
**Manufacturer:** Becton, Dickinson and Company



## Purpose of Submission

The purpose of this submission is to introduce a new product offering – the **BD PhaSeal™ Optima Connecting Set (C83-O)** and the **BD PhaSeal™ Optima Spike Set (C180-O)** – to the BD PhaSeal™ Optima family of devices.

## 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.

## Device Description

BD PhaSeal™ Optima Closed System 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 to prevent 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 for up to 10 penetrations.

The **BD PhaSeal™ Optima Connecting Set (C83-O)** is a sterile, single patient use sterile device that enables the administration of non-hazardous and hazardous parenteral drugs when used with the devices that have the compatible mating component - the BD PhaSeal™ Optima Spike Set and/or Connector. The BD PhaSeal™ Optima Connecting Set will be utilized by healthcare workers who administer parenteral hazardous drugs.

The **BD PhaSeal™ Optima Spike Set (C180-O)** is a sterile, single patient use sterile bag access device that enables the preparation and administration of non-hazardous and hazardous parenteral drugs when used with devices that have the compatible mating component - the BD PhaSeal™ Optima Injector and/or Connecting Set. The BD PhaSeal™ Optima Spike Set will be utilized by healthcare workers who prepare and administer parenteral hazardous drugs.



### **Technological Characteristics**

The **BD PhaSeal™ Optima Connecting Set (C83-O)** and the **BD PhaSeal™ Optima Spike Set (C180-O)** are considered substantially equivalent to the predicate device cleared per K181221 respectively. Any differences in technological characteristics such as the material were addressed through biocompatibility and performance testing. The biocompatibility and performance data demonstrated substantial equivalence and there were no new questions of safety or effectiveness. The subject devices were shown to be substantially equivalent in intended use, design, functionality, operating principles, materials, and performance characteristics to the predicate device.



### Technological Characteristics and Substantial Equivalence

The following table provides an overview of comparisons between the subject and the predicate device.

Attributes	Subject: BD PhaSeal™ Optima Connecting Set (C83-O) and Spike Set (C180-O)	Predicate: BD PhaSeal™ Optima Closed System Transfer Device	Equivalence Discussion
<b>510(k) Status</b>	Subject of 510(k)	K181221 Clearance date November 30, 2018	N/A
<b>Applicant</b>	Becton Dickinson, S.A.	Becton Dickinson, S.A.	Identical
<b>Review Branch</b>	General Hospital	General Hospital	Identical
<b>FDA Reg. Number</b>	21 CFR 880.5440	21 CFR 880.5440	Identical
<b>FDA Regulation Name</b>	Intravascular Administration Set	Intravascular Administration Set	Identical
<b>FDA Class</b>	Class II	Class II	Identical
<b>FDA Product Code</b>	ONB	ONB	Identical
<b>Indications for Use</b>	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 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.	Identical
<b>Devices of the CSTD System</b>	Protector, Injector, Connector, Infusion Adapter	Protector, Injector, Connector, Infusion Adapter	Identical
<b>Sterilization Method &amp; SAL</b>	Ethylene Oxide (EO) (SAL 10 <sup>-6</sup> )	Ethylene Oxide (EO) (SAL 10 <sup>-6</sup> )	Identical
<b>Sterilization Claim</b>	Content Sterile	Content Sterile	Identical
<b>Use</b>	Single Patient Use	Single Patient Use	Identical
<b>Biocompatibility</b>	Biocompatible for the intended use per ISO 10993-1	Biocompatible for the intended use per ISO 10993-1	Identical



Attributes	Subject: BD PhaSeal™ Optima Connecting Set (C83-O) and Spike Set (C180-O)	Predicate: BD PhaSeal™ Optima Closed System Transfer Device	Equivalence Discussion
<b>Duration of Use</b>	Up to 168 hours and/or 10 penetrations. <b>When the Injector (N40-O) component of the Connecting Set (C83-O) is engaged with the Spike Set (C180-O) for a long-term infusion, total activation time between the components should not exceed 24 hours.</b>	Up to 168 hours and/or 10 penetrations. <b>When the injector (N35-O) is paired with a connector (C35-O), continuous use of the injector not to exceed 24 hours.</b>	Substantially Equivalent – the duration of use is the same when the Injector is used with the mating BD PhaSeal™ Optima device
<b>Mating Method (action of device connections)</b>	Push on-Pull off	Push on-pull off	Identical
<b>Connection Between Devices within the System</b>	Collet style fitting with elastomeric double membranes	Collet style fitting with elastomeric double membranes	Identical
<b>Transfer Mechanism (responsible for airtight &amp; leak-proof connections)</b>	Elastomeric double membrane	Elastomeric double membrane	Identical
<b>Injector Needle Mechanism</b>	Collet-style fitting	Collet-style fitting	Identical
<b>Connection to Patient IV Line</b>	Infusion Adapter Port	<b>Luer Lock connection</b> or Infusion Adapter Port	Substantially Equivalent – the subject Connecting Set (C83-O) interfaces with the patient IV line using the same infusion adaptor port technology as the predicate Infusion Adaptor (C100-O).
<b>Injector Connection to External Device (e.g. syringe)</b>	Luer Lock	Luer Lock	Identical
<b>Minimize accidental disconnections Injector to IV line / syringe</b>	Luer lock design (dimensions) shall comply with the ISO 80369-7:2021 standard	Luer lock design (dimensions) shall comply with the ISO 80369-7:2021 standard	Identical



### **Substantial Equivalence Discussion:**

Design verification testing was performed to demonstrate that the subject device is equivalent to the predicate device. All test results met their acceptance criteria and support that the BD PhaSeal™ Optima Connecting Set (C83-O) and the BD PhaSeal™ Optima Spike Set (C180-O) are considered substantially equivalent to the predicate BD PhaSeal™ Optima Closed System Transfer Devices. The subject device and the predicates have equivalent indications for use and intended use. Both devices are sterile, single patient use devices that are sterilized via ethylene oxide.

Both the subject and predicate devices have the same principle of operation. The primary technological characteristics between the subject and the predicate devices are similar. The duration of the subject device and predicate are similar (up to 168 hours and/or 10 penetrations). When the injector or injector component is paired with a connector or IV-line, continuous use of the injector should not exceed 24 hours.

The BD PhaSeal™ Optima Connecting Set (C83-O) and the BD PhaSeal™ Optima Spike Set (C180-O) contain minor differences in technological characteristics when compared to the predicate device, however these differences do not change the intended use and do not raise new questions of safety and effectiveness as supported by verification and validation testing.

### **Safety and Performance Testing**

#### **Non-clinical Testing:**

The BD PhaSeal™ Optima Connecting Set and the BD PhaSeal™ Optima Spike Set were evaluated via non-clinical safety and performance testing to demonstrate that the subject devices are substantially equivalent to the predicate device.

The bench and nonclinical testing on the subject devices were conducted according to the following FDA recognized consensus standards listed below. The subject devices met applicable test specifications and acceptance criteria as described in the submission.

- ISO 8536-4:2019 (Partial Compliance to Section 7.4), Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (FDA Recognition Number 6-447)
- ISO 80369-1:2018, Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements (FDA Recognition Number 5-121)
- ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications (FDA Recognition Number 5-133)
- ISO 80369-20:2015, Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods (FDA Recognition Number 5-97)



- ISO 11135:2014/AMD 1:2018, Sterilization of health care products - Ethylene oxide: Requirements for development, validation, and routine control of a sterilization process for medical devices (FDA Recognition Number 14-529)
- ISO 11737-1:2018, Sterilization of health care products - Microbiological methods -- Part 1: Determination of a population of microorganisms on products [Including Amendment 1 (2021)] (FDA Recognition Number 14-577)
- ISO 11737-2:2019 Sterilization of health care products – Part 2: Microbiological methods – Tests of sterility performed in the definition, validation and maintenance of a sterilization process (FDA Recognition Number 14-540)
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (FDA Recognition Number 14-530)
- ISO 11607-2:2019 Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes (FDA Recognition Number 14-531)

### **Biocompatibility:**

Biocompatibility testing was completed in support of the safety of the BD PhaSeal™ Optima Connecting Set (C83-O) and BD PhaSeal™ Optima Spike Set (C180-O) in accordance with ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process and FDA Guidance, Use of International Standard 10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process”. The biocompatibility evaluation leveraged data from globally marketed and previously cleared BD devices, including predicate device submission K181221. Devices utilizing the same components, materials, manufacturing process, packaging, and/or sterilization method were selected as representative devices for biocompatibility testing.

The BD PhaSeal™ Optima Connecting Set (C83-O) has a medical device categorization per ISO 10993-1 as an externally communicating, blood path (indirect), prolonged (> 24 hours to 30 days) contacting device.

The BD PhaSeal™ Optima Spike Set (C180-O) has a medical device categorization per ISO 10993-1 as an externally communicating, blood path (indirect), limited (≤ 24 hours) contacting device.

### **Particulate Testing:**

The subject devices were tested to demonstrate the product meets particulate requirements of United States Pharmacopeia, National Formulary (USP), General Chapter <788>, Particulate Matter in Injections.

### **Microbial Ingress Testing:**

Microbial ingress was performed based on the following FDA guidance document:

- Guidance for Industry and FDA staff; Intravascular Administration Sets Premarket Notification Submissions [510(k)], July 11, 2008



**Clinical Data:**

Not Applicable. Clinical data was not considered necessary to demonstrate substantial equivalence to the predicate.

**Conclusion:**

The information provided in this submission, including the non-clinical safety and performance testing, is sufficient to demonstrate substantial equivalence of the BD PhaSeal™ Optima Connecting Set and Spike Set to the predicate device. The subject and predicate devices have the same indications for use, the same intended use, and similar technological characteristics. Any differences between the subject and predicate device are minor and do not raise new questions of safety and effectiveness.