

510(K) Summary of Safety and Effectiveness

JAN 09 2013

Date Prepared: 12 October 2012

1. **Submitted By:**

John Roberts
Regulatory Affairs Specialist
BD Medical - Medical Surgical Systems
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 5473; Fax: 201 847 5307

2. **Device Name:**

Trade Name: BD PhaSeal® Closed System Drug Transfer Device
Common Name: Closed antineoplastic & hazardous drug reconstitution & transfer system
Classification Name: Intravascular administration set
Classification: Class II, 21 CFR 880.5440

3. **Predicate Device:**

BD PhaSeal® Connector, Injector, Protector – K120384

4. **Device Description:**

The PhaSeal® System is a sterile single-used closed system drug transfer device. The closed transfer of liquid takes place through a double membrane utilizing self-sealing elastomeric membranes, tightly fitted together through a bayonet fitting on all PhaSeal components. A single lumen cannula perforates the double membranes for the transfer of liquid. 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 and spills and also minimizing the risk of microbial contamination.

5. **Indications for Use:**

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 or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.

6. **Technological Characteristics:**

The technological characteristics of the subject device are identical to those of the predicate devices.

Characteristic	Subject Device: BD PhaSeal	Predicate Device: BD PhasSeal K120384	Equivalence
Transfer Mechanism	Elastomeric Double Membrane	Elastomeric Double Membrane	Identical to Predicate
Connection between PhaSeal Components	Bayonet Fitting with Elastomeric Double Membrane	Bayonet Fitting with Elastomeric Double Membrane	Identical to Predicate
Components	Protector, Injector, Connector	Protector, Injector, Connector	Identical to Predicate
Protector Spike	Stainless Steel or Plastic	Stainless Steel or Plastic	Identical to Predicate
Injector Cannula	Stainless Steel	Stainless Steel	Identical to Predicate
Fitting Connection to external standard syringe	Injector: Luer / Luer Lock Connection	Injector: Luer / Luer Lock Connection	Identical to Predicate
Fitting Connection to external standard IV line	Luer Lock or Spike Port	Luer Lock or Spike Port	Identical to Predicate
Fitting Connection to external standard IV bag	Spike	Spike	Identical to Predicate
Needle Safety Feature (Injector Only)	Safety sleeve	Safety sleeve	Identical to Predicate
Sterilization Method	EO	EO	Identical to Predicate

7. **Performance:**

The additional tests referenced in the table have been provided in order to substantiate the use of product code ONB - Closed antineoplastic and hazardous drug reconstitution and transfer system – for the BD PhaSeal® Closed System Drug Transfer Device. BD has included the additional airtight and leakproof requirement as both of these requirements are cited by the National Institute for Occupational Safety and Health (NIOSH) and the International Society of Oncology Pharmacy Practitioners (ISOPP) as essential requirements necessary to reduce health care workers from exposure to hazardous drugs. In addition, NIOSH also cites the need to prevent contaminants from entering the closed system during transfer. As such, BD proposes to extend the microbial ingress claim to the entire system; not just the PhaSeal Protector. As there is no change to the subject device in comparison to the predicate devices, the performance data provided represent the performance of both the predicate and subject device of this 510(k).

Item#	Performance Specification:	Status of BD PhaSeal® System
1	Leakproof Connections	No Leaks (Fluorescein Test) ^{1,2}
2	Airtight Connections	No Visible Smoke (TiCl ₄ Test) ³
3	Microbial Ingress	No Ingress at the Protector or Connector

8. **Conclusion:**

Based on comparison to the predicate device and the nonclinical tests provided, the modified BD PhaSeal® Closed System Drug Transfer Device is as safe, as effective, and performs as well as the legally marketed predicate device.

¹ Spivey S, Connor T. Determining sources of workplace contamination with antineoplastic drugs and comparing conventional IV drug preparation with a closed system. *Hosp Pharm.* 2003; 38(2): 135-139.

² Jorgenson J, Spivey S, Au C et al. Contamination comparison of transfer devices intended for handling hazardous drugs. *Hosp Pharm.* 2008; 43(9): 723-727

³ *Ibid.*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 9, 2013

Mr. John Roberts
Regulatory Affairs Specialist
Becton Dickinson & Company
1 Becton Drive
MC237
FRANKLIN LAKES NJ 07417

Re: K123213
Trade/Device Name: PhaSeal[®] - Closed System Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: ONB
Dated: October 12, 2012
Received: October 15, 2012

Dear Mr. Roberts:

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.

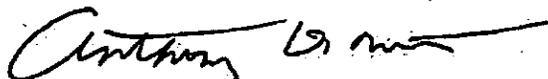
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123213

Device Name: PhaSeal® – A Closed System Transfer Device

Indications for Use:

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 or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page ___ of ___

Sajjad H.
Syed

Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Sajjad H. Syed,
0.9.2342.19200300.100.1.1=200601742
Date: 2013.01.09 15:12:01 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123213