K121050

Date Prepared 7 February 2013

510(k) Summary

FEB 7 2013

1. **Submitted By:**

Avital Merl
Staff Regulatory Affairs Specialist
BD Medical - Medical Surgical Systems
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 4739
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2. **Device Name:**

Trade Name: 1) 0.9% Sodium Chloride Injection, USP, BD PosiFlush Flush Syringe
2) 0.9% Sodium Chloride Injection, USP, BD PosiFlush SF Flush Syringe

Common Name: 0.9% Sodium Chloride Injection Flush Syringe
Classification Name: Saline, Vascular Access Flush
Classificiation: Class II, 21 CFR § 880.5200

3. **Predicate Device:**

Trade Name: 0.9% Sodium Chloride Injection, USP, BD Pre-Filled Flush Syringe
Manufacturer: Becton, Dickinson and Company
510(k) Number: K003553

Trade Name: 0.9% Sodium Chloride Injection, USP, BD PosiFlush SF Flush Syringe
Manufacturer: Becton, Dickinson and Company
510(k) Number: K042061

4. **Device Description:**

The modified BD PosiFlush Flush Syringe is a three-piece, sterile, single use syringe with a 6% (Luer) connector pre-filled with 0.9% Sodium Chloride Injection, USP and sealed with a tip cap. BD has altered the modified device from the predicate by changing the stopper material and adding an extra thread to the plunger rod, threaded stopper insert. All performance characteristics are equivalent to the predicate device. The 0.9% Sodium Chloride Injection, USP BD PosiFlush Flush Syringes are intended for use in maintaining patency of vascular access devices (VAD's).

This submission represents two 2 devices: the BD PosiFlush Flush Syringe, which is provided with a sterile fluid path; and the BD PosiFlush Flush SF Syringe, which is provided externally sterile for use on a sterile field. Both configurations are sterilized via moist heat.

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5. **Intended Use**:

BD PosiFlush™ Normal Saline Flush Syringes are intended to be used only for the flushing of indwelling vascular access devices. 10ml BD PosiFlush™ Normal Saline Flush Syringes are generally compatible for use with syringe pumps.

6. **Technological Characteristics:**

The principal device of this 510(k) premarket notification is the result of a design change to the predicate device (K003553 and K042061) conducted in accordance with Quality System Regulations, 21 CFR § 820. The BD PosiFlush Flush Syringe is Substantially Equivalent to the predicate device, given that:

a) The BD PosiFlush Flush Syringe has the same intended use as the predicate device
b) The BD PosiFlush Flush Syringe operates under the same operating principle as the predicate device
c) The BD PosiFlush Flush Syringe barrel and stopper use a design identical to the predicate device.
d) The BD PosiFlush Flush Syringe barrel and plunger rod use materials identical to the predicate device.
e) The BD PosiFlush Flush Syringe pre-filled 0.9% Sodium Chloride Injection solution meets the requirements of USP 34<11>: Sodium Chloride Injection, as does the predicate device.
f) The BD PosiFlush Flush Syringe meets the requirements of ISO 10993 as applicable to the intended use of the device, as does the predicate device.
g) The BD PosiFlush Flush Syringe are sterilized to an SAL of 10^{-6} (sterile fluid path or externally sterile) via a Moist Heat sterilization process, as does the predicate device.
h) The BD PosiFlush Flush Syringe demonstrated equivalent performance to the predicate device during design verification testing.

6. **Performance:**

Design Verification testing included the following:

Table VI – Modified Device Performance

Performance Characteristic	Acceptance Criteria
Functional Testing	
Container Closure Integrity	No Dye in Solution; No Leakage in the luer well or tip threads; No Leakage Past the Stopper Ribs; No Dye Between Stopper Ribs
Break Loose Force	Equivalence to Predicate
Break Out Force	Equivalence to Predicate
Sustaining Force	Equivalence to Predicate
Pump Force	10ml/hr – 20N 1ml/hr – 13N

	0.1ml/hr – 9N
Dead Space / Expelled Volume	Equivalent to labeled volume (3ml, 5ml or 10ml)
Syringe Induced Reflux	0 average reflux when connected to a 4 Fr catheter

Sodium Chloride Injection, USP Testing

Baxterial Endotoxin	Per USP <85>
Particulate Matter	Per USP <788>
Assay of NaCl	Per USP <11>
Heavy Metals	Per USP <231>
Iron	Per USP <241>
UV/vis	Per USP <851>
pH	Per USP <791>

Biocompatibility Testing

Test	**Method/Acceptance**
Cytotoxicity	Per ISO10993-5:1999, Non-Toxic
Hemolysis	Per ISO10993-4:2002/A:2006, Non-Toxic
Acute Systemic Toxicity	Per ISO10993-11:2006, Non-Toxic
Intracutaneous Reactivity	Per ISO10993-10:2002/A1:2006, Non-Irritant
Sensitization	Per ISO10993-10:2002/A1:2006, Non-Sensitizer
Bacterial Mutagenicity	Per ISO10993-3, Non-Mutagenic
In Vitro Mouse Lymphoma	Per ISO10993-3, Non-Mutagenic
Mouse Embryo Assay	Per ISO10993-3, Non-Mutagenic
Ocular Irritation	Per ISO10993-10:2002/A1:2006, Non-Irritant,
Rabbit Pyrogen	Per ISO10993-11:2006, Non-Pyrogenic
Subchronic Intracutaneous Toxicity	Per ISO10993-11:2006, Non-Toxic
Chemical Extractables Analysis	LC/DAD/MS & GC/MS, No significant extractables

Design Verification tests were performed based on the risk analysis conducted, and the results of these tests demonstrate that the BD PosiFlush Flush Syringe performed in an equivalent manner to the predicate device and is safe and effective when used as intended.

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

February 7, 2013

Ms. Avital Merl
Staff Regulatory Affairs Specialist
Becton, Dickinson and Company
One Becton Drive
FRANKLIN LAKES NJ 07417

Re: K121050
Trade/Device Name: 0.9% Sodium Chloride Injection, USP BD PosiFlush Flush Syringe
0.9% Sodium Chloride Injection, USP BD PosiFlush SF Flush Syringe
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NGT
Dated: February 1, 2013
Received: February 4, 2013

Dear Ms. Merl:

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/ucm115809.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" (21CFR 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): K121050

Device Name: 0.9% Sodium Chloride Injection, USP BD PosiFlush Flush Syringe

Model Number	*Syringe Size/Fill Volume*
306544	3mL BD PosiFlush™ SP
306545	5mL BD PosiFlush™ SP
306546	10mL BD PosiFlush™ SP with Regular Plunger Rod
306547	10mL BD PosiFlush™ SP
306553	10mL BD PosiFlush™ SF with Regular Plunger Rod
306549	3mL BD PosiFlush™ SP with BPC (Blunt Plastic Cannula)
306550	5mL BD PosiFlush™ SP with BPC
306551	10mL BD PosiFlush™ SP (Regular Plunger Rod) with BPC

Indications for Use:

BD PosiFlush™ Normal Saline Flush Syringes are intended to be used only for the flushing of indwelling vascular access devices. Catalog No. 306547 10ml BD PosiFlush™ Normal Saline Flush Syringes are generally compatible for use with syringe pumps.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____