



Food and Drug Administration  
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April 4, 2016

Becton, Dickinson and Company  
John Blewitt  
Regulatory Affairs Manager  
1 Becton Drive  
Franklin Lakes, NJ 07417

Re: K153481

Trade/Device Name: 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe  
Regulation Number: 21 CFR 880.5200  
Regulation Name: Intravascular Catheter  
Regulatory Class: II  
Product Code: NGT  
Dated: March 4, 2016  
Received: March 7, 2016

Dear Mr. Blewitt:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**  
**Clinical Deputy Director**  
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
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Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K153481

Device Name

0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe

Indications for Use (Describe)

The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringes are intended to be used only for the flushing of indwelling vascular access devices.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary

Submitted By: John Blewitt  
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Becton, Dickinson and Company  
Medication and Procedural Solutions  
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Phone: (201)847-5473; Fax: (201)847-5307

Date Prepared: April 1, 2016

Trade Name: 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe

Common Name: 0.9% Sodium Chloride Injection Flush Syringe

Classification Name: Saline, Vascular Access Flush

Classification Regulation: 21 CFR §880.5200

Class: Class II

Product Code: NGT

Predicate Device: K121050  
0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP and SF Syringe

### Device Description

The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe is a three-piece, sterile, single use syringe with a 6% (luer) connector prefilled with 0.9% sodium chloride injection, USP, and sealed with a tip cap. The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe is sterilized via moist heat and provided externally sterile for use on a sterile field.

### Intended Use

The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringes are intended to be used only for the flushing of indwelling vascular access devices.

### Comparison of Technological Characteristics

The subject 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe is equivalent to that of the predicate 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe in intended use, materials and performance characteristics. The subject device 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe, includes a change from Tyvek to new primary packaging materials consisting of medical grade paper and multi-layer film. Based on results of performance testing conducted, the subject device is substantially equivalent to the predicate device.

## Performance

Performance Testing conducted to support substantial equivalence

<b>Performance Characteristic</b>	<b>Predicate Device</b> K121050: 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe	<b>Subject Device</b> 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe
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### 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	Identical to predicate
Break Loose Force	No leakage beyond stopper ribs	Identical to predicate
Break Out Force	Acceptable forces required to remove plunger rod	Identical to predicate
Sustaining Force	Consistent plunger rod forces	Identical to predicate
Pump Force	10ml/hr – 20N 1ml/hr – 13N 0.1ml/hr – 9N	Identical to predicate
Dead Space / Expelled Volume	Equivalent to labeled volume on barrel	Identical to predicate
Syringe Induced Reflux	0 average reflux when connected to a 4 Fr catheter	Identical to predicate
Package Integrity	Per ISO 11607	Equivalent to predicate
Package Stability	Per ISO 11607	Equivalent to predicate

### Sodium Chloride Injection, USP Testing

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

### Biocompatibility Testing

Cytotoxicity	Per ISO10993-5:1999, Non-Toxic	Identical to predicate
Hemolysis	Per ISO10993-4:2002/A:2006, Non-Toxic	Identical to predicate
Acute Systemic Toxicity	Per ISO10993-11:2006, Non-Toxic	Identical to predicate
Intracutaneous Reactivity	Per ISO10993-10:2002/A1:2006, Non-Irritant	Identical to predicate
Sensitization	Per ISO10993-10:2002/A1:2006, Non-Sensitizer	Identical to predicate
Bacterial Mutagenicity	Per ISO10993-3, Non-Mutagenic	Identical to predicate
In Vitro Mouse Lymphoma	Per ISO10993-3, Non-Mutagenic	Identical to predicate
Mouse Embryo Assay	Per ISO10993-3, Non-Mutagenic	Identical to predicate
Ocular Irritation	Per ISO10993-10:2002/A1:2006,	Identical to predicate

	Non-Irritant,	
Rabbit Pyrogen	Per ISO10993-11:2006, Non-Pyrogenic	Identical to predicate
Subchronic Intracutaneous Toxicity	Per ISO10993-11:2006, Non-Toxic	Identical to predicate
Chemical Extractables Analysis	LC/DAD/MS & GC/MS, No significant extractables	Identical to predicate

### **Clinical Testing**

Clinical testing was not required for this submission.

### **Substantial Equivalence Statement**

The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringes are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate devices.

### **Conclusion**

The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringes have been validated to meet the established performance criteria. The results of the analysis and verification studies demonstrate that the 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF syringes are substantially equivalent to the predicate devices.