510(k) Summary - K141311

JUL 2 5 2014

Submitted By:	Juma Hoshino Regulatory Affairs Specialist BD Medical – Medical Surgical Systems 1 Becton Drive Franklin Lakes, NJ 07417 Phone: (201)847-4260; Fax: (201)847-5307
Date Prepared:	July 24, 2014
Trade Name:	0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringe 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 (Class II, 21 CFR §880.5200)
Product Code:	NGT
Predicate Device:	K121050 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringe 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringe

Device Description

The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP and SF Syringe (also referred to as BD PosiFlush™ SP and 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 BD PosiFlush™ SP Syringe is provided with a sterile fluid path, and the BD PosiFlush™ SF Syringe is provided externally sterile for use on a sterile field. Both configurations are sterilized via moist heat. The modified BD PosiFlush™ SP Syringe and BD PosiFlush™ SF Syringe, the subject of this 510(k), includes a new resin material in the barrel of the prefilled syringe.

Intended Use

The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringes and 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringes are intended to be used only for the flushing of indwelling vascular access devices. Catalog Number 306547 10 mL 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringes are generally compatible for use with syringe pumps.

Technological Characteristics

The subject BD PosiFlush™ SP and SF Syringe is equivalent to that of the predicate BD PosiFlush™ SP and SF Syringe in intended use, materials and performance characteristics. The new syringe barrel resin material does not raise any new questions regarding safety or effectiveness.

Element of Comparison		Equivalence
Syringe Materials	Barrel	Equivalent to predicate.
	Plunger Rod	Identical to predicate.
	Stopper	Identical to predicate.
	Stopper Lubricant	Identical to predicate.
	Tip Cap	Identical to predicate.
Solution		Identical to predicate.
Sterilization Method		Identical to predicate.
Sterile		Identical to predicate.
SAL		Identical to predicate.
Shelf Life		Identical to predicate.

Non-Clinical Testing

BD has performed the following non-clinical testing based on the risk analysis conducted and the results of these tests demonstrate that the BD PosiFlush™ SP and SF Syringe performed in an equivalent manner to the predicate device and is safe and effective when used as intended.

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
	Retaining Ring Force	Equivalence to Predicate
	Tip Cap Removal Force	Equivalence to Predicate
Sodium Chloride Injection, USP, Testing	Bacterial Endotoxin	Per USP Monograph, Sodium Chloride Injection
	Particulate Matter	
	Assay of NaCl	
	Heavy Metals	
	Iron	
	pH	
Biocompatibility Testing		Per ISO10993 Series LC/DAD/MS, GC-MS, ICP; acceptable extractable test.

Clinical Testing

Clinical testing was not required for this submission.

Substantial Equivalence Statement

The 0.9 % Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringes and 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. The modified device does not raise new concerns of safety and effectiveness.

Conclusion

The 0.9 % Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringes and 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 BD PosiFlush™ SP and SF Syringes perform as intended and based on the non-clinical tests performed the subject device is as safe, as effective and performs as safely and effectively as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-000

July 25, 2014

Becton, Dickinson and Company
Ms. Juma Hoshino
Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K141311
Trade/Device Name: 0.9% Sodium Chloride Injection, USP BD PosiFlush SP Syringe
0.9% Sodium Chloride Injection, USP BD PosiFlush SF Syringe
Regulation Number: 21 CFR 880.5200
Regulation Name: Saline, Vascular Access Flush
Regulatory Class: II
Product Code: NGT
Dated: June 24, 2014
Received: June 25, 2014

Dear Ms. Hoshino

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 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. 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,

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, 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): K141311

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

Indications for Use:

The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringes and 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Syringes are intended to be used only for the flushing of indwelling vascular access devices. Catalog Number 306547 10 mL 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000540490, cn=Sreekanth Gutala -S
Date: 2014.07.25 10:22:08 -04'00'