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 2, 2017

Becton Dickinson And Company
John Blewitt
Regulatory Affairs Manager
1 Becton Drive
Franklin Lakes, New Jersey 07045

Re: K161552
Trade/Device Name: 0.9% Sodium Chloride Injection, USP BD PosiFlush SP Syringe
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: NGT
Dated: June 3, 2016
Received: June 6, 2016

Dear John 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,

Michael J. Ryan -S

for Tina Kiang, PhD
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161552

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

Indications for Use *(Describe)*
The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringe is intended to be used only for the flushing of indwelling vascular access devices. Catalog Number 306547 10 mL BD PosiFlush™ SP Syringes are generally compatible for use with syringe pumps.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Special 510(k) Summary

Submitted By: John Blewitt
Regulatory Affairs Manager
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417
Phone: (201)847-5473
Fax: (201)847-5307

Date Prepared: January 4, 2017

Subject Devices:	Trade Name:	0.9 % Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringe
	Common Name:	0.9% Sodium Chloride Injection Flush Syringe
	Classification:	Class II, 21 CFR §880.5200, Saline, Vascular Access Flush
	Product Code:	NGT
Predicate Devices:	Trade Name:	0.9 % Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringe
	510(k) Reference:	K141311
	Common Name:	0.9% Sodium Chloride Injection Flush Syringe
	Classification:	Class II, 21 CFR §880.5200, Saline, Vascular Access Flush
	Product Code:	NGT

Device Description
The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP (also referred to as BD PosiFlush™ SP 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, which is sterilized via moist heat.

The change described in this submission is the qualification of a supplier specific formulation for stopper material for 0.9 % Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringes.

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

Technological Characteristics
The subject BD PosiFlush™ SP Syringes are equivalent to that of the predicate BD PosiFlush™ SP Syringes in intended use, fundamental scientific technology, operating principles, product design, and performance characteristics.

Device Characteristics	Subject Device BD PosiFlush™ SP Syringe (K161552)	Predicate Device BD PosiFlush™ SP Syringe (K141311)
Manufacturer	Becton, Dickinson and Company	Becton, Dickinson and Company
Intended Use	The BD PosiFlush™ SP Syringe is intended to be used only for the flushing of indwelling vascular access devices (VAD's). Catalog number 306547 10 mL BD PosiFlush™ SP Syringes are generally compatible for use with syringe pumps.	The BD PosiFlush™ SP Syringe is intended to be used only for the flushing of indwelling vascular access devices (VAD's). Catalog number 306547 10 mL BD PosiFlush™ SP Syringes are generally compatible for use with syringe pumps.
Operating Principle	The BD PosiFlush™ SP 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.	The BD PosiFlush™ SP 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.
Materials	Barrel: Polypropylene Plunger Rod: Polypropylene Tip Cap: Polypropylene w/ White Colorant Stopper Lubricant: Silicone Stopper Material: Styrene-butadiene rubber	Barrel: Polypropylene Plunger Rod: Polypropylene Tip Cap: Polypropylene w/ White Colorant Stopper Lubricant: Silicone Stopper Material: Styrene-butadiene rubber
Packaging	Flow wrap Shelf Carton Case Carton	Flow wrap Shelf Carton Case Carton
Specification	0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringe is provided in 3 mL, 5 mL and 10 mL configurations. All three sizes utilize a consistent 10 mL syringe barrel diameter	0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringe is provided in 3 mL, 5 mL and 10 mL configurations. All three sizes utilize a consistent 10 mL syringe barrel diameter
Sterilization	Per ISO 17665	Per ISO 17665
SAL Level	SAL 10^{-6}	SAL 10^{-6}
Shelf Life	3 Years	3 Years
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1

Performance Data

Modifications to BD PosiFlush™ SP Syringes were evaluated using a risk management process. This risk assessment process was performed in accordance with ISO14971. The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility evaluation was conducted in accordance with the FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," June 16, 2016. The battery of testing included the following tests and assessments. Cytotoxicity (per ISO10993-5), Hemolysis (per ISO10993-4), Acute systemic toxicity (per ISO10993-11), Sub-Chronic Toxicity (Per ISO10993-11), Intracutaneous reactivity (per ISO10993-10), Ocular irritation (per ISO 10993-10), Partial thromboplastin Time (ISO 10993-4), Sensitization (per ISO10993-10), Pyrogenicity (per ISO 10993-11), Genotoxicity (per ISO 10993-3) and Chemical extractable analysis (per ISO 10993-18).

Design Verification testing was also conducted to ensure the device met the predetermined acceptance criteria for the following tests; Container Closure Integrity, Break Loose/Break Out/Sustaining force, Stopper Separation, Leakage, Pump Force, Ship Test, Dead Space, Syringe Induced Reflux were performed to demonstrate that the subject device met predetermined acceptance criteria per BD's internal specification.

Substantial Equivalence

The BD PosiFlush™ SP Syringes have been verified to meet the established performance criteria above. The results of design verification testing demonstrate that the modifications made to the subject device do not affect the safety and efficacy of the device and demonstrated the same intended use, fundamental scientific technology and operating principles.

Conclusion

The subject BD PosiFlush™ SP Syringes are substantially equivalent to the legally marketed predicate device, BD PosiFlush™ SP Syringes (K141311).