



Food and Drug Administration
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Silver Spring, MD 20993-0002

Becton Dickinson And Company
Aakash Jain
Senior Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07045

February 27, 2017

Re: K163591

Trade/Device Name: BD Posiflush Heparin Lock Flush Syringe
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: NGT
Dated: December 16, 2016
Received: December 20, 2016

Dear Aakash Jain:

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,



For Tina Kiang
Acting 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

510(k) Number (if known)

Device Name

The Heparin Lock Flush Solution, USP, BD PosiFlush™ Heparin Lock Flush Syringe

Indications for Use (Describe)

The Heparin Lock Flush Solution, USP, BD PosiFlush™ Heparin Lock Flush Syringes are intended for maintenance of patency of vascular access devices only.

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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Special 510(k) Summary

Submitted By: Aakash Jain
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Date Prepared: February 8, 2017

Subject Devices: Trade Name: Heparin Lock Flush Solution, USP-
BD PosiFlush™ Heparin Lock Flush Syringe
Common Name: Heparin, Vascular Access Flush
Classification: Class II, 21 CFR §880.5200
Product Code: NZW

Predicate Devices: Trade Name: Heparin Lock Flush Solution, USP-
BD PosiFlush™ Heparin Lock Flush Syringe
510(k) Reference: K090680
Common Name: Heparin, Vascular Access Flush
Classification: Class II, 21 CFR §880.5200
Product Code: NZW

Device Description

Heparin Lock Flush Solution, USP, BD PosiFlush™ Heparin Lock Flush Syringe (also referred to as BD PosiFlush™ Heparin Lock Flush Syringe) is provided in either 10 or 100 Units/mL concentrations in 0.9% Sodium Chloride Injection, USP packaged in a plastic, disposable, single use syringe. The syringe is a three-piece, single use syringe with a 6% (luer) connector prefilled with Heparin Lock Flush Solution, and sealed with a tip cap. The BD PosiFlush™ Heparin Lock Flush Syringe is provided in a 3mL or 5mL size configuration. The BD PosiFlush™ Heparin Lock Flush Syringe is provided with a sterile fluid path, sterilized via moist heat. The solution is delivered through the vascular access device to maintain catheter patency and is not to be used for anticoagulation therapy.

The change described in this submission is to qualify a new stopper material used in the BD PosiFlush™ Heparin Lock Flush Syringe.

Intended Use

The Heparin Lock Flush Solution, USP, BD PosiFlush™ Heparin Lock Flush Syringe are intended for maintenance of patency of vascular access devices only.

Technological Characteristics

The subject BD PosiFlush™ Heparin Lock Flush Syringe are equivalent to that of the predicate BD PosiFlush™ Heparin Lock Flush Syringe in intended use, fundamental scientific technology, operating principles, product design, and performance characteristics.

Device Characteristics	Subject Device BD PosiFlush™ Heparin Lock Flush Syringe (K163591)	Predicate Device BD PosiFlush™ Heparin Lock Flush Syringe (K090680)
Manufacturer	Becton, Dickinson and Company	Becton, Dickinson and Company
Intended Use	The Heparin Lock Flush Solution, USP, BD PosiFlush™ Heparin Lock Flush Syringes are intended for maintenance of patency of vascular access devices only.	The Heparin Lock Flush Solution, USP, BD PosiFlush™ Heparin Lock Flush Syringes are intended for maintenance of patency of vascular access devices only.
Operating Principle	The BD PosiFlush™ Heparin Lock Flush Syringe is a three-piece, sterile, single use syringe with a 6% (Luer) connector pre-filled with heparin sodium, USP in either 10U/mL or 100U/mL concentration 0.9% Sodium Chloride Injection, USP, and sealed with a tip cap.	The BD PosiFlush™ Heparin Lock Flush Syringe is a three-piece, sterile, single use syringe with a 6% (Luer) connector pre-filled with heparin sodium, USP in either 10U/mL or 100U/mL concentration 0.9% Sodium Chloride Injection, USP, and sealed with a tip cap.
Materials	Barrel: Polypropylene Plunger Rod: Polypropylene Tip Cap: Polypropylene w/ Blue (10 units/mL) or Yellow (100 units/mL) Colorant Stopper Lubricant: Silicone Stopper Material: Bromobutyl Rubber	Barrel: Polypropylene Plunger Rod: Polypropylene Tip Cap: Polypropylene w/ Blue (10 units/mL) or Yellow (100 units/mL) Colorant Stopper Lubricant: Silicone Stopper Material: Styrene-butadiene Rubber
Packaging	Flow wrap Shelf Carton Case Carton	Flow wrap Shelf Carton Case Carton
Specification	Provided in 3 mL and 5 mL in either 10U/mL or 100U/mL configurations. All sizes utilize a consistent 10 mL syringe barrel diameter.	Provided in 3 mL and 5 mL in either 10U/mL or 100U/mL configurations. All sizes utilize a consistent 10 mL syringe barrel diameter.

Device Characteristics	Subject Device BD PosiFlush™ Heparin Lock Flush Syringe (K163591)	Predicate Device BD PosiFlush™ Heparin Lock Flush Syringe (K090680)
Shelf Life	10U/mL- 18 Months 100U/mL- 24 Months	10U/mL- 18 Months 100U/mL- 24 Months
Sterilization	Per ISO 17665	Per ISO 17665
SAL Level	SAL 10 ⁻⁶	SAL 10 ⁻⁶
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1

Performance Data

Modifications to BD PosiFlush™ Heparin Lock Flush Syringe 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 (ISO10993-4), 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™ Heparin Lock Flush 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™ Heparin Lock Flush Syringes are substantially equivalent to the legally marketed predicate device, BD PosiFlush™ Heparin Lock Flush Syringes (K090680)