July 21, 2023

Becton, Dickinson and Company
Samhitha Mohan
Sr. Staff Regulatory Affairs Specialist
1 Becton Dr
Franklin Lakes, New Jersey 07417

Re: K231161
Trade/Device Name: 0.9% Sodium Chloride Injection, USP BD PosiFlush™ SF Saline Flush Syringe
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: NGT
Dated: April 24, 2023
Received: April 24, 2023

Dear Samhitha Mohan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K231161

Device Name
0.9% Sodium Chloride Injection, USP BD PosiFlush™ SF Saline Flush Syringe

Indications for Use *(Describe)*
The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Saline Flush 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.**

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

## 510(k) Summary (21 CFR §807.92)

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|---|---|---|
| **Submitter Information** | Submitter Name: | Becton, Dickinson and Company |
| | Submitter Address: | 1 Becton Dr<br>Franklin Lakes<br>NJ 07417 |
| | Contact Person: | Samhitha Mohan<br>Sr. Staff Regulatory Affairs Specialist |
| | Email Address: | Samhitha.Mohan@bd.com |
| | Phone Number: | (214)-971-0979 |
| | Fax Number: | (201)-847-5307 |
| | Date of Preparation: | 21 July, 2023 |
| **Subject Device** | Trade Name: | 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Saline Flush Syringe |
| | Common Name: | 0.9% Sodium Chloride Injection Flush Syringe |
| | Regulation Number: | 21 CFR 880.5200 |
| | Device Class: | Class II |
| | Classification Name: | Saline, Vascular Access Flush |
| | Product Code: | NGT |
| | Classification Panel: | General Hospital |
| **Predicate Device** | Trade Name: | 0.9% Sodium Chloride Injection, USP BD PosiFlush™ SF Syringe |
| | 510(k) Number: | K153481 |
| | Classification Name: | Saline, Vascular Access Flush |
| | Regulation Number: | 21 CFR 880.5200 |
| | Regulatory Class: | Class II |
| | Product Code: | NGT |
| | Classification Panel: | General Hospital |

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| **Device Description** | 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Saline Flush Syringe is a polypropylene syringe intended to flush indwelling vascular access devices. It is a sterile, single use syringe prefilled with 0.9% sodium chloride injection, USP, and sealed with a tip cap. The device is packaged in a film-on-film blister pack and sterilized by gamma irradiation. External sterility of the device enables it to be used in the sterile field.<br><br>The subject device is available only in 10mL syringe configuration. |
| **Indications for Use** | The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Saline Flush Syringes are intended to be used only for the flushing of indwelling vascular access devices. |
| **Technological Characteristic-s** | The following table provides a comparison between the subject and predicate devices – |

| Attribute | Subject Device (0.9% Sodium Chloride Injection, USP BD PosiFlush™ SF Saline Flush Syringe) | Predicate Device (0.9% Sodium Chloride Injection, USP BD PosiFlush™ SF Syringe) – K153481 | Compar -ison |
|---|---|---|---|
| Intended Use/Indications for Use | The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SF Saline Flush Syringes are intended to be used only for the flushing of indwelling vascular access devices. | 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. | Similar; "Saline Flush" is added to the name of the subject device |
| Operating Principle | The tip cap is twisted off from the barrel and plunger rod is depressed to drive the flow of 0.9% sodium chloride USP solution through the indwelling vascular access devices. The saline solution 'cleans out' or displaces any other fluid and maintains patency of the line. | The tip cap is twisted off from the barrel and plunger rod is depressed to drive the flow of 0.9% sodium chloride USP solution through the indwelling vascular access devices. The saline solution 'cleans out' or displaces any other fluid and maintains patency of the line. | Identical |
| Syringe Configuration | 10mL | 10mL | Identical |
| Single Use? | Yes | Yes | Identical |
| Sterile? | Yes | Yes | Identical |
| Use in Sterile Field? | Yes | Yes | Identical |
| Content of syringe package | One pre-filled syringe per pack | One pre-filled syringe per pack | Identical |

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|---|---|---|---|
| Device Components | • Barrel<br>• 0.9% NaCl USP solution<br>• Plunger Rod<br>• Tip Cap<br>• Stopper | • Barrel<br>• 0.9% NaCl USP solution<br>• Plunger Rod<br>• Tip Cap<br>• Stopper | Identical |
| Barrel Material | Polypropylene-Polyethylene Random Copolymer | Polypropylene Homopolymer | Similar; Subject device material is assessed as per ISO 10993-1 |
| Barrel Lubricant | Silicone | Silicone | Identical |
| Plunger Rod Material | Polypropylene | Polypropylene | Identical |
| Stopper Material | Styrene-Butadiene Rubber | Styrene-Butadiene Rubber | Identical |
| Stopper Lubricant | Silicone | Silicone | Identical |
| Tip Cap Material | Polypropylene-Polyethylene Random Copolymer | Polypropylene Homopolymer | Similar; Subject device material is assessed as per ISO 10993-1 |
| Tip Cap Colorant | White | White | Identical |
| Packaging Configuration | • Blister pack<br>• Shelf Carton<br>• Case Carton | • Blister pack<br>• Shelf Carton<br>• Case Carton | Identical |
| Primary Packaging Material | Film on film | Paper on film | Different; Appropriate packaging tests are performed to ensure sterile barrier integrity is maintained |
| Mode of Sterilization | Gamma | Autoclave | Different |
| SAL | $10^{-6}$ | $10^{-6}$ | Identical |

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|---|---|---|---|
| Shelf Life | 1 year | 3 years | Different; Subject device shelf life has been assessed by appropriate bench performance testing |
| Tip Cap Removal Torque | Measure the torque required to remove the tip cap from the syringe | Measure the torque required to remove the tip cap from the syringe | Same as Predicate |
| Tip Cap Leakage | Measure the resistance to leakage in between the Luer and the tip cap for pre-filled syringes | Measure the resistance to leakage in between the Luer and the tip cap for pre-filled syringes | Same as Predicate |
| Breakloose Force | Measure the initial maximum force required to move the plunger rod/stopper in the syringe barrel | Measure the initial maximum force required to move the plunger rod/stopper in the syringe barrel | Same as Predicate |
| Breakout Force | Measure the maximum force required to move the plunger rod/stopper in the syringe barrel a short time after initially moving the plunger rod/stopper | Measure the maximum force required to move the plunger rod/stopper in the syringe barrel a short time after initially moving the plunger rod/stopper | Same as Predicate |
| Sustaining Force | Measure the average force required to move the plunger rod/stopper in the syringe barrel | Measure the average force required to move the plunger rod/stopper in the syringe barrel | Same as Predicate |
| Reflux | Measure the potential blood reflux into the catheter from PosiFlush™ SF syringe | Measure the potential blood reflux into the catheter from PosiFlush™ SF syringe | Same as Predicate |

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| Retaining Ring Force | Measure the force necessary to remove the plunger rod / stopper assembly from the syringe barrel after assembly | Measure the force necessary to remove the plunger rod / stopper assembly from the syringe barrel after assembly | Same as Predicate |
| Leakage past Stopper | Measure the resistance to leakage in between the barrel and stopper for pre-filled syringes | Measure the resistance to leakage in between the barrel and stopper for pre-filled syringes | Same as Predicate |
| Expelled Volume | Measure the volume of saline solution | Measure the volume of saline solution expelled from the syringe | Same as Predicate |
| Sterility | To verify $10^{-6}$ Sterility Assurance Level (SAL) on all surface (fluid path and external surface) of syringe, fluid path and inside surface of primary packaging | To verify $10^{-6}$ Sterility Assurance Level (SAL) on all surface (fluid path and external surface) of syringe, fluid path and inside surface of primary packaging | Same as Predicate |
| NaCl Solution Stability | Following tests to comply with 0.9% NaCl Injection USP Monograph – NaCl Assay, pH, Endotoxin, Particulate Matter, Iron, Heavy metals, UV/Vis | Following tests to comply with 0.9% NaCl Injection USP Monograph – NaCl Assay, pH, Endotoxin, Particulate Matter, Iron, Heavy metals, UV/Vis | Same as Predicate |
| Cytotoxicity | Non-cytotoxic | Non-cytotoxic | Same as Predicate |
| Sensitization | Non-Sensitizer | Non-Sensitizer | Same as Predicate |
| Irritation or Intracutaneous Activity | Non-irritant | Non-irritant | Same as Predicate |
| Acute Systemic Toxicity | No acute systemic toxicity | No acute systemic toxicity | Same as Predicate |

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| Material Mediated Pyrogenicity | Not a material mediated-pyrogen | Not a material mediated-pyrogen | Same as Predicate |
| Hemocompatibility | Non-hemolytic | Non-hemolytic | Same as Predicate |
| Genotoxicity | Non-genotoxic | Non-genotoxic | Same as Predicate |
| LAL Endotoxin | Below the Endotoxin Limit 0.5 EU/device | Below the Endotoxin Limit 0.5 EU/device | Same as Predicate |
| Extractable and Leachable Analysis | Extractable and leachable substances showed toxicologically acceptable levels. | Extractable and leachable substances showed toxicologically acceptable levels. | Under the condition of the chemical characterization testing, there were no extractables and leachables identified that indicated significant risk concerns |

**Discussion:**

The subject device and predicate device are different with respect to the following items:

1. "Saline Flush" is added to the name of the subject device
2. The mode of sterilization was changed from autoclave (predicate) to gamma irradiation (subject). The gamma sterilized test samples were evaluated for performance, packaging integrity and biocompatibility.
3. The barrel and tip cap resin of both subject and predicate device is polypropylene. However, the subject device polypropylene has small amount of polyethylene which ensures compatibility with gamma sterilization process. Appropriate performance tests and biocompatibility tests were performed to ensure safety and effectiveness.
4. The blister pack was changed from paper on film to film on film material. This change ensures compatibility with gamma sterilization process. Package integrity tests were performed to evaluate the material change.
5. The shelf life of the subject device is lowered to 1 year. Stability tests were performed to support 1 year shelf life of the subject device.

The different technological characteristics between the subject and predicate device are evaluated in bench performance testing, packaging integrity and biocompatibility tests demonstrating that there are no new or different questions of safety and effectiveness.

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| **Non-Clinical Testing** | BD has performed the following performance tests in accordance with 21 CFR §820.30 to demonstrate that the PosiFlush™ SF Syringe performs equivalent to the predicate devices.<br><br>The following tests were performed on the subject device to an internal specification or a Standard: |

| Test | Purpose | Acceptance Criteria | Result |
|---|---|---|---|
| **Performance/Design Verification Tests** | | | |
| Tip Cap Removal Torque | Measure the torque required to remove the tip cap from the syringe | Tip Cap can be twisted off as per BD validated force | Pass |
| Reflux | Measure the potential blood reflux into the catheter from PosiFlush™ SF syringe | Reflux greater than BD validated internal value | Pass |
| Tip Cap Leakage | Evaluate the resistance to leakage between the barrel Luer and the tip cap for pre-filled syringes | No evidence of Tip Cap leakge | Pass |
| Leakage past Stopper | Evaluate the resistance to leakage between the barrel and stopper ribs | No leakage of solution past the stopper ribs | Pass |
| Breakloose force | Measure the initial maximum force required to move the plunger rod/stopper in the syringe barrel | Force to move plunger rod/stopper is less than the BD validated force | Pass |
| Breakout Force | Measure the maximum force required to move the plunger rod/stopper in the syringe barrel a short time after initially moving the plunger rod/stopper | | Pass |
| Sustaining Force | Measure the average force required to move the plunger rod/stopper in the syringe barrel | | Pass |
| Retaining Ring Force | Measure the force necessary to remove the plunger rod/stopper assembly from the syringe barrel after assembly | Force to move plunger rod/stopper is greater than the BD validated force | Pass |
| Expelled Volume | Measure the volume of saline solution expelled from the syringe | USP43-NF38 <697>Container Content for Injections | Pass |
| NaCl Assay | Measure the NaCl concentration saline solution in syringe samples | 0.9% NaCl Injection USP Monograph | Pass |
| pH | Measure the pH of saline solution in syringe samples | 0.9% NaCl Injection USP Monograph and USP43-NF38 <791> pH | Pass |
| Iron | Measure the amount of iron in saline solution | 0.9% NaCl Injection USP Monograph and | Pass |

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| | | USP43-NF38 <241> Iron | |
| Heavy Metals | Measure the heavy metals such as Cadmium, Arsenic, Cobalt, Vanadium, Copper, Lead, Nickel, Lithium, Antimony and Mercury in saline solution | USP43-NF38 <232> Elemental Impurities - Limits | Pass |
| NaCl solution weight loss | Measure the weight loss of saline solution in pre-filled saline syringes | USP43-NF38 <671> Containers Performance Testing | Pass |
| UV Analysis | Measure the UV absorbance between 220-360 nm for pre-filled saline syringes | < 0.4 AU | Pass |
| Bacterial Endotoxin | Determine the amount of endotoxin in saline pre-filled syringes | 0.9% NaCl Injection USP Monograph and USP43-NF38 <85> Bacterial Endotoxins Test | Pass |
| Sterility | To verify $10^{-6}$ SAL in the fluid path. | Sterile; No growth in media | Pass |
| Surface Sterility | To verify $10^{-6}$ SAL on all surface of syringe and inside surface of primary packaging | | Pass |
| Particulate Matter | Measure the number of particulates in saline pre-filled syringes | USP43-NF38 <788> Particular Matter in Injections | Pass |
| Appearance and Solution Clarity/ Barrel Transparency | Examine the appearance, solution clarity and barrel transparency in pre-filled saline syringes | Solution and components are clear | Pass |
| Primary Package Integrity | Evaluates the sterile barrier system of the pre-filled syringe throughout shelf life | No leaks when tested by Vacuum Bubble Leak (ASTM F2096-11) | Pass |
| | | Non-porous | Pass |
| | | Seal strength and width value as per BD validated force and width measurements respectively | Pass |

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| | | No defects in packaging seals when visually inspected | Pass |
| | | Clean peel of blister pack with no foreign matter | Pass |
| **Biocompatibility** | | | |
| Cytotoxicity | ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity | Grade ≤ 2 | Pass |
| Sensitization | ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization | Non-Sensitizer | Pass |
| Irritation | ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests for Irritation | Final Test Sample Score ≤ 1 | Pass |
| Acute Systemic Toxicity | ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity | No significantly greater biological reaction than the control | Pass |
| Material Mediated Pyrogenicity | ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity<br><br>USP43-NF38 <151>Pyrogen Test (USP Rabbit Test) | No temperature rise ≥ 0.5° C | Pass |
| Hemocompat -ibility | ISO 10993-4:2017 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood<br><br>ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials | ≤ 5% hemolysis | Pass |
| Genotoxicity | ISO 10993-3: 2014 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity | Non-mutagenic | Pass |
| LAL Endotoxin | USP 43-NF38 <161> Medical Devices – Bacterial Endotoxin | Below the Endotoxin Limit 0.5 EU/device | Pass |

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| | USP43-NF38 <85> Bacterial Endotoxins Test<br><br>ANSI AAMI ST72:2019 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing | | |
| Extractable and Leachable Analysis | ISO 10993-18: 2020 Biological evaluation of medical devices - Part 18: Chemical characterization of materials<br><br>ISO 10993-17: 2002 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances | N/A | See **Note 1** below |

**Note 1:** Under the condition of the chemical characterization testing, there were no extractables and leachables identified that indicated significant risk concerns

The subject device met all the predetermined acceptance criteria for the above listed performance, packaging, and biocompatibility tests.

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| **Clinical Testing** | Not applicable. |
| **Conclusion** | The conclusions drawn from the nonclinical tests demonstrate that the BD PosiFlush™ SF is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K153481. |