December 2, 2025

Becton, Dickinson and Company
Anamika Tiwari
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K250884
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: November 4, 2025
Received: November 5, 2025

Dear Anamika Tiwari:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection
Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250884

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

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.

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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0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP Saline Flush Syringe
510(k) Summary (21 CFR §807.92)

K250884

Submitter Information	Submitter Name:	Becton, Dickinson, and Company
	Submitter Address:	1 Becton Drive, Franklin Lakes, NJ 07417
	Contact Person:	Anamika Awadhesh Tiwari Staff Regulatory Affairs Specialist
	Email Address:	Anamika.tiwari@bd.com
	Phone Number:	201.847.5005
	Fax Number:	201.847.5307
	Date of Preparation:	December 1st, 2025
Subject Device	Trade Name:	0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringe
	Model Number:	306546
	Common Name:	0.9% Sodium Chloride Injection Flush Syringe
	Regulation Number:	21 CFR 880.5200
	Classification Name:	Saline, Vascular Access Flush
	Regulatory Class:	Class II
	Product Code:	NGT
	Classification Panel:	General Hospital
Predicate Device	510(k) Number:	K161552
	Trade Name:	0.9 % Sodium Chloride Injection, USP, BD PosiFlush™ SP Syringe
	Common Name:	0.9% Sodium Chloride Injection Flush Syringe
	Regulation Number:	21 CFR 880.5200
	Classification Name:	Saline, Vascular Access Flush
	Regulatory Class:	Class II
	Product Code:	NGT
	Classification Panel:	General Hospital

Device Description	BD PosiFlush™ SP Syringe is a three-piece, single use syringe with a Luer connector that is compatible with ISO 80369-7:2021 small-bore connectors for liquids and gases in healthcare applications- Part 7: Connectors for intravascular or hypodermic applications. The syringe is prefilled with 0.9% sodium chloride injection, USP and sealed with a tip cap. PosiFlush™ SP Syringe is individually packaged inside a flow wrap. The moist heat sterilization process renders the syringe a Sterility Assurance Level of 10^{-6} for the fluid path and saline solution.
Indications for 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.
Technological Characteristics	The following table provides a comparison between the subject and predicate devices.

Attribute	Subject Device (BD PosiFlush™ SP Syringe) K250884	Predicate Device (BD PosiFlush™ SP Syringe (K161552)	Comparison
Intended Use/ Indications for 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.	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.	Similar (306547 is not in scope of this 510k)
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.	Identical
Syringe Configuration	10 mL	3, 5, and 10mL	Different
Single Use?	Yes	Yes	Identical
Sterile?	Sterile Fluid Path	Sterile Fluid Path	Identical
Use in Sterile Field?	No	No	Identical
Content of syringe package	One pre-filled syringe per flow wrap pack	One pre-filled syringe per flow wrap pack	Identical
Device Components	• Barrel • 0.9% NaCl USP solution • Plunger Rod • Tip Cap • Stopper	• Barrel • 0.9% NaCl USP solution • Plunger Rod • Tip Cap • Stopper	Identical

Barrel Material	Polypropylene	Polypropylene	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	Polypropylene	Similar (Subject device material is assessed as per ISO 10993-1)
Tip Cap Colorant	White	White	Identical
Packaging Configuration	• Flow Wrap • Shelf Carton • Case Carton	• Flow Wrap • Shelf Carton • Case Carton	Identical
Primary Packaging Material	Flow wrap	Flow wrap	Identical
Mode of Sterilization	Moist Heat	Moist Heat	Identical
SAL	10^{-6}	10^{-6}	Identical
Shelf Life	1 year	3 years	Different
Biocompatibility testing	• Cytotoxicity • Sensitization • Intracutaneous Reactivity • Material-mediated Pyrogenicity • Acute Systemic Toxicity	• Cytotoxicity • Hemolysis • Acute systematic toxicity • Sub Chronic Toxicity • Intracutaneous Reactivity • Ocular Irritation	Different

	• Hemocompatibility	• Partial Thromboplastin Time • Sensitization • Pyrogenicity • Genotoxicity • Chemical extractable analysis	
Performance testing	• Tip Cap Removal Torque • Reflux • Tip Cap Leakage • Leakage past Stopper • Break loose force • Breakout Force • Sustaining Force • Retaining Ring Force • Expelled Volume • NaCl Chemistry Testing • Particulate Analysis • Appearance and Solution Clarity • Barrel Transparency • Distribution Test	• Container Closure Integrity • Break loose force • Breakout force • Sustaining force • Stopper Separation • Leakage • Pump Force • Distribution Test • Dead Space • Syringe Induced Reflux	Different

Discussion	The subject device and predicate device are different with respect to the following item: 1. The barrel and tip cap resin of both subject and predicate device is different. 2. The subject device's configuration includes the 10ml, when compared to the 3ml, 5ml, and 10mL configurations of the predicate device. The different technological characteristics between the subject and predicate device are evaluated in performance testing, biocompatibility tests, and distribution tests demonstrating that there are no new or different questions of safety and effectiveness.
Non-Clinical Testing	BD has performed the following performance tests in accordance with 21 CFR §820.30 to demonstrate that the PosiFlush™ SP Syringe performs equivalent to the predicate devices. 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™ SP 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 leakage	Pass
Leakage past Stopper	Evaluate the resistance to leakage between the barrel and stopper ribs	No leakage of solution past the stopper ribs	Pass
Break loose 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 USP43-NF38 <241> Iron	Pass
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 Analysis	Measure the number of particulates in saline pre-filled syringes	≥ 10 µm < 3,000 ≥ 25 µm < 300	Pass
Appearance and Solution Clarity/ Barrel Transparency	Examine appearance, solution clarity and barrel transparency in pre-filled saline syringes	Solution and components are clear	Pass
Distribution Test	Evaluates the product and packaging integrity after distribution.	No unit packaging open seal (end or fin) cuts, tears or holes greater than BD validated internal value.	Pass
		No fluid between specified stopper ribs	Pass
		Container Closure Integrity maintained	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 or Intracutaneous Activity	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 USP43-NF38 <151>Pyrogen Test (USP Rabbit Test)	No temperature rise ≥ 0.5° C	Pass
Hemocompat-ability	ISO 10993-4:2017 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials	≤ 5% hemolysis	Pass
Particulate Analysis	Measure the number of particulates in saline pre-filled syringes	≥ 10 µm < 3,000 ≥ 25 µm < 300	Pass

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

Clinical Testing	Not applicable.
Conclusion	The conclusion drawn from the nonclinical test demonstrates that the subject device 0.9% Sodium Chloride Injection, USP BD PosiFlush SP Syringe is as safe, as effective, and performs as well as or better than the legally marketed predicate device K161552.