July 16, 2022

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

Re: K213955
Trade/Device Name: BD PosiFlush SafeScrub
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: QTI
Dated: June 29, 2022
Received: July 1, 2022

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, M.D., Ph.D
Acting 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)*
K213955

Device Name
BD PosiFlush™ SafeScrub

Indications for Use *(Describe)*
The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SafeScrub prefilled flush syringe with an integrated disinfection unit is intended to be used as a disinfection cleaner for needleless access devices attached to indwelling vascular access devices (VADs) and flushing of these VADs.

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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BD PosiFlush™ SafeScrub – K213955

510(k) Summary (21 CFR §807.92)

Submitter Information	Submitter Name: Submitter Address: Contact Person: Email Address: Phone Number: Fax Number: 510(k) Number: Date of Preparation:	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes NJ 07417 Samhitha Mohan Staff Regulatory Affairs Specialist Samhitha.Mohan@bd.com (214) 971-0979 (201) 847-5307 K213955 July 15, 2022
Subject Device	Trade Name: Common Name: Regulation Number: Device Class: Classification Name: Classification Product Code: Classification Panel:	BD PosiFlush™ SafeScrub Pre-filled Saline Syringe with Disinfection Unit 21 CFR 880.5200 Class II Saline, Vascular Access Flush QTI General Hospital
Primary Predicate Device	Trade Name:	0.9% Sodium Chloride Injection, USP BD PosiFlush™ SP Syringe

	510(k) Number: Classification Name: Regulation Number: Regulatory Class: Product Code: Classification Panel:	K161552 Saline, Vascular Access Flush 21 CFR 880.5200 Class II NGT General Hospital
Predicate Device	Trade Name: 510(k) Number: Classification Name: Regulation Number: Regulatory Class: Product Code: Classification Panel:	SiteScrub IPA Device K112791 Pad, Alcohol, Device Disinfectant Unclassified Unclassified LKB General Hospital
Device Description	BD PosiFlush™ SafeScrub is a sterile, single use pre-filled saline syringe with integrated Disinfection Unit (DU). The polypropylene syringe contains 0.9% sodium chloride (USP) solution with a tip cap that is modified at the distal end to accommodate DU. The DU has high density polyethylene housing with 70% Isopropyl Alcohol (IPA) solution in low density polyethylene foam. The pre-filled syringe with modified syringe tip cap is sterilized by moist heat and the DU is sterilized by gamma irradiation. The subject device is available only in 10mL syringe configuration.	
Indications for Use	The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SafeScrub prefilled flush syringe with an integrated disinfection unit is intended to be used as a disinfection cleaner for needleless access devices attached to indwelling vascular access devices (VADs) and flushing of these VADs.	
Technological Characteristic-s	The following table provides a comparison between the subject and predicate devices –	

Attribute	Subject Device (BD PosiFlush™ SafeScrub)	Primary Predicate Device (0.9% Sodium Chloride Injection, USP BD PosiFlush™ SP Syringe) – K161552	Predicate Device (SiteScrub IPA Device) – K112791	Comparison
Intended Use/Indications for Use	The 0.9% Sodium Chloride Injection, USP, BD PosiFlush™ SafeScrub prefilled flush syringe with an integrated disinfection unit is intended to be used as a disinfection cleaner for needleless access devices attached to indwelling vascular access devices (VADs) and flushing of these VADs.	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.	The Site-Scrub IPA Device is intended for use on injection ports and female Luer hubs as a disinfecting cleaner.	The intended use of the subject device is created by combining the intended use of both the predicates. The subject device's intended use does not include pump compatible statement since PosiFlush™ SafeScrub is not intended to be used with pumps. Additionally, subject device's intended use refers to injection ports and female Luer hubs as needleless access devices.
Operating Principle	Same as predicates	The pre-filled USP 0.9% saline syringe flushes indwelling vascular access devices	70% IPA solution i.e., antimicrobial agent and active mechanical friction from the foam aids in disinfection	Identical

Disinfectio-n Time	Same as predicate	N/A	Twist back and forth for at least 8 repetitions, for a minimum of 10 seconds	Identical
Target microorganisms for *in vitro* antimicrob-ial efficacy	• Staphylococcus aureus • Staphylococcus epidermidis • Escherichia coli • Pseudomonas aeruginosa • Candida albicans • Candida glabrata • Acinetobacter baumannii	N/A	• Staphylococcus aureus • Staphylococcus epidermidis • Escherichia coli • Pseudonomona aeruginosa • Candida albicans • Candida parapsilosis	Identical except for Acinetobacter baumannii, Candida glabrata and Candida parapsilosis. In vitro antimicrobial efficacy testing was performed for all the microorganisms
Syringe Configura-tion	10mL only	3mL, 5mL and 10mL	N/A	Subject device does not include 3 and 5mL syringe configurations
Device Compone-nts	• Barrel • 0.9% NaCl solution • Plunger Rod • Modified Tip Cap • Stopper Lubricant • Stopper • Modified Housing • Foam • 70% IPA solution	• Barrel • 0.9% NaCl solution • Plunger Rod • Tip Cap • Stopper Lubricant • Stopper	• Housing • Foam • 70% IPA solution	All the components are identical in design with the exception of tip cap and housing. The distal end of tip cap and DU housing are modified to snap fit with each other to form PosiFlush™ SafeScrub
Barrel Material	Same as predicate	Polypropylene	N/A	Identical

Plunger Rod Material	Same as predicate	Polypropylene	N/A	Identical
Stopper Material	Same as predicate	Styrenebutadiene rubber	N/A	Identical
Stopper Lubricant Material	Same as predicate	Silicone	N/A	Identical
Tip Cap Material	Same as predicate	Polypropylene w/ White Colorant	N/A	Identical
DU Housing Material	Same as predicate w/white colorant	N/A	High Density Polyethylene (HDPE) w/blue colorant	HDPE material in DU is identical to SiteScrub's housing material. The subject device's DU has white colorant to match with the color of the tip cap. Colorant differences are assessed as per ISO 10993-1
Foam Material	Same as predicate	N/A	Low Density Polyethylene (LDPE)	Identical
Foam Base Colorant	Same as predicate	N/A	Copper phthalocyanine blue	Identical

Packaging Configuration	Same as predicates	• Flow wrap • Shelf Carton • Case Carton	Top Foil	Identical with the exception of top foil material. Appropriate packaging tests are performed to ensure top foil maintains sterile barrier to the DU
Sterilization Mode	Same as predicates	Moist heat	Gamma	Identical
SAL	Same as predicates	10^{-6} (Sterile Fluid Path)	10^{-6} (Sterile Fluid Path)	Identical
Shelf Life	0.5 years	3 years	9 months	Subject device shelf life has been assessed by appropriate bench performance testing

Discussion:

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

1. The intended use of the subject device is identical to the predicates with the exception of pump compatibility statement since PosiFlush™ SafeScrub is not intended to be used with infusion pumps. The subject device refers to injection ports and female Luer hubs as needleless access devices. Needleless access devices include needlefree connector, Y-sites, and stopcocks.
2. PosiFlush™ SafeScrub is created by combining the predicate devices (K161552 and K112791). The distal end of tip cap of PosiFlush SP syringe (K161552) and the housing of SiteScrub IPA Device (K112791) are dimensionally modified to integrate such that they remain attached to each other at all times. This integration/interface is evaluated by torque rotation and axial pull force tests throughout the shelf life.

   NOTE: The modified SiteScrub IPA Device in PosiFlush™ SafeScrub is referred as Disinfection Unit (DU).

3. The microorganisms targeted by DU in the *in vitro* antimicrobial efficacy test were chosen based on the current literature search for microorganisms that cause catheter related bloodstream infection.
4. The material of top foil which creates a seal on the DU housing has been updated from the SiteScrub IPA Device to comply with ISO 11607-1:2019 and for vendor consolidation purposes. Similar to the predicate device, the new top foil material also ensures that it retains sterile barrier integrity and accordingly packaging tests such as vacuum bubble leak test, peel force test, seal width, visual inspection, and porosity tests are performed.
5. Since the colorant of DU housing is changed from blue to white, appropriate biocompatibility tests are performed as per ISO 10993-1 to ensure the safe use of PosiFlush™ SafeScrub. The biocompatibility tests performed on the DU are identified below. The colorant was changed from blue to white to match with the color of tip cap.
6. The subject device is also evaluated throughout its shelf life by bench performance testing to ensure that the device meets the predetermined acceptance criteria.

The different technological characteristics between the subject and predicate device are evaluated in bench performance testing, in vitro antimicrobial efficacy, packaging integrity, and biocompatibility tests demonstrating that the different technological characteristics do not raise any 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.

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			
Container Closure Integrity	Evaluate sterile barrier system for the syringe	No dye within the syringe	Pass
Leakage Test		No leakage from the syringe	Pass

	Torque Removal Test	Evaluate tip cap removal	Tip Cap can be twisted off as per BD validated force	Pass
	Sterile Fluid Path	Evaluate the syringe's fluid path sterility	SAL: 10^{-6}	Pass
	Axial Pull Force	Evaluate the potential separation of Tip Cap from Disinfecting Unit (DU)	DU cannot be pulled off per BD validated force	Pass
	Torque		DU cannot be twisted off as per BD validated force	Pass
	Particulate Ingress	Evaluate per USP <788>	USP <788>	Pass
	Antimicrobial Efficacy	Evaluate disinfection efficacy of the DU	$\geq$ 4-log reduction	Pass
	70% IPA Concentrat-ion	Evaluate IPA concentration over shelf life for the DU	70±7%	Pass
	Foam Rotation	Evaluate foam rotation during use	Foam should not rotate >90 degrees within the DU housing during use	Pass
	Foam Retention	Evaluate foam retention before and during use	Foam must be retained within the DU	Pass
		Evaluate foam retention after use	Foam must be retained within DU after scrubbing	Pass
	Foam Durability	Evaluate foam for evidence of ripped or ragged material and debris or particulate	No ripped or ragged material and debris or particulate	Pass
	Foam Compressibili	Evaluate foam for wetness and compressibility	Foam must be wet and compressible	Pass

	ty and Wetness			
	70% IPA Ingress	Evaluate IPA ingress that may enter the patient IV line	Maximum dose of 2 mg IPA/kg body mass/day per US EPA	Pass
	Package integrity of DU	Evaluate sterile barrier system of the DU	Bubble Leak as per ASTM F2096	Pass
			Seal Width ≥ 0.58 mm	Pass
			No delamination	Pass
			Peel Force shall be within: USL: ≤12.9 N LSL: ≥3.69 N	Pass
			Microbial properties as per ISO 11607-1:2019	Pass
	Biocompatibility			
	Cytotoxicity	ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Grade ≤ 2	Pass
	Sensitization	ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Non-Sensitizer	Pass

Irritation or Intracutaneous Activity	ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	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	No temperature rise ≥ 0.5° C	Pass
Hemocompatibility	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
LAL Endotoxin	USP 43-NF38 <161> Medical Devices – Bacterial Endotoxin	Below the Endotoxin Limit 20 EU/device	Pass
Extractable and Leachable Analysis	ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of materials	N/A	Toxicolo-gical Risk Assessm-ent

The 2 main components of BD PosiFlush™ SafeScrub are sterilized as follows:

1. Pre-filled saline syringe with modified syringe tip cap is sterilized by moist heat

	2. DU is sterilized by gamma irradiation The subject device met all the predetermined acceptance criteria for the above listed performance tests.
Clinical Testing	Not applicable.
Conclusion	The BD PosiFlush™ SafeScrub is as safe and as effective and performs as well as or better than the legally marketed devices, 0.9% Sodium Chloride Injection, USP BD PosiFlush SP Syringe and SiteScrub IPA Device.