July 29, 2025

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

Re: K251350
Trade/Device Name: BD Plastipak™ Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: April 30, 2025
Received: April 30, 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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology 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)*
K251350

Device Name
BD Plastipak™ Syringe

Indications for Use *(Describe)*
The BD Plastipak™ Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.

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."

K251350
BD Plastipak™ Syringe
510(k) Summary (21 CFR §807.92)

Submitter Information	Submitter Name:	Becton, Dickinson, and Company
	Submitter Address:	1 Becton Drive, Franklin Lakes NJ 07417
	Contact Person:	Anamika Tiwari Sr. Regulatory Affairs Specialist
	Email Address:	Anamika.tiwari@bd.com
	Phone Number:	(201) 847-4760
	Fax Number:	(201)-847-5307
	Date of Preparation:	30th June 2025
Subject Device	Trade Name:	BD Plastipak™ Syringe
	Common Name:	Piston Syringe
	Regulation Number:	21 C.F.R. § 880.5860
	Regulation Name:	Syringe, Piston
	Regulatory Class:	Class II device
	Product Code:	FMF
	Classification Panel:	General Hospital
Predicate Device	Trade Name:	BD Single Use, Hypodermic Syringe
	510(k) Reference:	K980987
	Common Name:	Piston Syringe
	Regulation Number:	21 C.F.R. § 880.5860
	Regulation Name:	Syringe, Piston
	Regulatory Class:	Class II
	Product Code:	FMF
	Classification Panel:	General Hospital

Device Description	The BD Plastipak™ Syringe is a three-piece, single use, sterile, hypodermic syringe with a 6% (Luer) male connector in 20 mL and 50 mL eccentric luer slip tip configurations. The BD Plastipak™ Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection. The syringe assembly consists of a lubricated polypropylene barrel with a graduated scale, a lubricated synthetic rubber stopper and a polypropylene plunger rod. The plunger rod is pulled back to aspirate fluids or depressed to inject or expel fluids. The syringe barrel incorporates a male 6% (Luer) connector which is connectable to a compatible female 6% (Luer) connector. The BD Plastipak™ Syringe is provided sterile by Ethylene Oxide Gas (ETO) sterilization method.
Indications for Use	The BD Plastipak™ Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.
Technological Characteristics	The following table provides a comparison between the subject and predicate devices.

Attributes		Subject Devices	Predicate Devices	Comparison
Intended Use/ Indications for Use		The BD Plastipak™ Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.	The BD Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.	Identical
Operating Principle		Piston Syringe	Piston Syringe	Identical
Syringe configuration		• 20ml • 50 ml (Available in Luer-Slip, Eccentric Tip configuration)	• 1ml • 3 ml • 5 ml • 10 ml • 20 ml • 30 ml • 50 ml (Available in Luer-lok, Luer-Slip, Eccentric Tip configuration)	Different (The syringe sizes covered in the subject submission are within the range of the predicate device sizes)
Single Use		Yes	Yes	Identical
Sterile		Yes	Yes	Identical
Use in Sterile field		Yes	Yes	Identical
Device Components	Barrel resin	Polypropylene (HPR35CMD)	Polypropylene (PH-712B)	Different
	Barrel Lubricant	Silicone Lubricant	Silicone Lubricant	Identical
	Barrel Ink	Black Ink	Black Ink	Identical
	Plunger Rod	Polypropylene	Polypropylene	Identical
	Stopper	Polyisoprene Rubber	Polyisoprene Rubber	Identical
	Stopper Lubricant	Silicone Lubricant	Silicone Lubricant	Identical
Packaging Configuration		• Blister pack (Primary)	• Blister pack (Primary)	Identical
		• Shelf Carton (Secondary)	• Shelf Carton (Secondary)	
Packaging Material		• Primary- Direct seal paper on Polymer Film	• Primary- Direct seal paper on Polymer Film	Identical
		• Secondary- Corrugated cardboard	• Secondary- Corrugated cardboard	

Content of syringe package	Sterile:	One syringe per pack (Blister Pack)	One syringe per pack (Blister Pack)	Identical
Sterilization Method		ETO	ETO	Identical
SAL		10^{-6}	10^{-6}	Identical
Shelf Life		5 years	5 years	Identical

Discussion	The subject device and predicate device are different with respect to the following item: 1. Change in component material (Barrel resin and supplier) The purpose of this premarket submission is to introduce new barrel resin material and supplier for the BD Hypodermic Syringe cleared under K980987. Change is being made to allow contingency and reduce supply chain risk of BD Plastipak™ Syringe (subject device). The predicate device covered in Premarket notification K980987 are available in additional volumes i.e., 1ml, 3ml, 5ml, 10ml, 20ml, 30ml and 50ml sizes in Luer- lok, Luer- Slip, & Eccentric tip configuration. The subject device will be available in 20 ml and 50 ml Luer-Slip, Eccentric tip configuration that are covered within the range of the predicate device. Only 20 ml and 50 ml BD Plastipak™ Syringe are affected by the change described in the subject 510(k) Premarket Notification. No change will be made to the product's intended use, technological design, or performance. The different technological characteristics between the subject and predicate device are evaluated in bench performance testing, and biocompatibility tests demonstrating that there are no new questions or modified risk 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 BD Plastipak™ Syringe performs equivalent to the predicate device. These tests were performed on the subject device to an internal specification or a Standard:

Performance Testing	
Test	**Purpose**
Breakout Force	ISO 7886-1:2017- Performance evaluation of force to operate the piston.
Sustaining Force	ISO 7886-1:2017- Evaluation of force to operate the piston.
Leakage Past Stopper	ISO 7886-1:2017- Evaluation of Freedom from air and liquid leakage past plunger stopper.
Volumetric Accuracy	ISO 7886-1:2017- Evaluation of Volumetric Accuracy
Dead Space	ISO 7886-1:2017- Evaluation of residual volume
Luer Leakage	ISO 80369-7:2021 - Evaluation of the luer fittings for leakage
Stress Cracking	ISO 80369-7:2021- Evaluation of the luer fittings for stress cracking
Resistance to separation from axial load	ISO 80369-7:2021- Evaluation of the luer fitting for separation when subjected to axial force.
Biocompatibility	
Cytotoxicity	ISO 10993-5:2009- Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
Sensitization	ISO 10993-10:2021- Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization
Intracutaneous Reactivity	ISO 10993-23:2021- Biological evaluation of medical devices- Test for Irritation
Acute Systemic Toxicity	ISO 10993-11:2017- Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
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)
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

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

Clinical Testing	Not applicable.
Summary of Substantial Equivalence	The differences between predicate and the subject device do not raise any new questions or modified risks of safety or effectiveness when compared. Therefore, BD Plastipak™ Syringe is substantially equivalent to the predicate device cleared under K980987.