March 14, 2019

Becton, Dickinson and Company
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

Re: K182589
Trade/Device Name: BD Plastipak Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 14, 2019
Received: February 15, 2019

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182589

Device Name
BD Plastipak™ Syringe

Indications for Use *(Describe)*
The BD Plastipak™ Syringe is intended for single 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.

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

Submitter:
Leslie Robinson-Frye
Staff Regulatory Affairs Specialist
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417

Phone: (201) 847-6891
Fax: (201) 847-4306

Contact Person: Leslie Robinson-Frye
Date Prepared: March 13, 2019

Subject Devices:

Name of Device:	BD Plastipak™ Syringe
Common Name:	Piston Syringe
Classification Name:	Piston Syringe, (21 CFR §880.5860)
Regulatory Class:	II
Product Code:	FMF

Predicate Devices:

Name of Device:	Becton Dickinson Single Use Hypodermic Syringes
510(k) Reference:	K980987
Common Name:	Piston Syringe
Classification:	Piston Syringe, (21 CFR §880.5860, Class II device)
Product Code:	FMF

This predicate has not been subject to a design-related recall.

Reason for Submission

The purpose of this submission is to modify the stopper material, barrel/stopper lubricant, stopper dimensions, stopper manufacturing location, product name, and label statements (pump claim and do not re-sterilize) of the predicate Becton Dickinson Single Use Hypodermic Syringes.

Device Description

The 3mL and 20mL BD Plastipak™ Syringe is a three-piece, single use, sterile or bulk non-sterile (BNS) hypodermic syringe with Luer Slip or male 6% (Luer Lock) conical lock connection, which are connectable to a compatible female 6% (Luer) connector. The syringe assemblies consist of a lubricated polypropylene barrel with a graduated scale, a lubricated thermoplastic elastomer stopper and a polypropylene plunger rod. The plunger rod is pulled back to aspirate fluids or depressed to inject or expel fluids. The barrel scale of the BD Plastipak™ Syringe incorporates a scale graduated in units of milliliters.

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The BD Plastipak™ Syringe is provided sterile by Irradiation or Ethylene Oxide Gas (EtO) sterilization methods in a syringe only configuration or with a BD Hypodermic Needle, BD SafetyGlide™ Hypodermic Needle or BD Eclipse™ Hypodermic Needle. The BD Plastipak™ Syringe is also provided in a bulk non-sterile, syringe only configuration.

Intended Use
The BD Plastipak™ Syringe is intended for single use by health care professionals for general purpose fluid aspiration/injection.

Comparison of Technological Characteristics
The subject BD Plastipak ™ Syringe is equivalent to that of the predicate BD Hypodermic Syringe in intended use, materials and performance characteristics.

The stopper material, lubricant and dimensions are different between the subject and predicate devices However, the above differences are not critical in the safety and effectiveness of the device when used as labeled as demonstrated through functional testing.

Element of Comparison		Subject Device	Predicate Device
Indications for Use/Intended Use		The BD Plastipak™ Syringe is intended for single use by health care professionals for general purpose fluid aspiration/injection.	These syringes are intended for use by health care professionals for general purpose fluid aspiration/injection.
Syringe Materials	**Plunger**	Polypropylene	Polypropylene
	Barrel	Polypropylene	Polypropylene
	Barrel Silicone	Silicone	Silicone
	Stopper	Thermo Plastic Elastomer (TPE) Copolymer	Polyisoprene Rubber
	Stopper Silicone	Silicone	Silicone
Syringe Dimensions	**Stopper**	- Stopper Outer Diameter -Stopper Inner Diameter	- Stopper Outer Diameter -Stopper Inner Diameter
Sterilization Methods		EtO	EtO
		Irradiation	Irradiation
SAL		10-6	10-6
Shelf Life		5 Years	5 Years
Functional Testing:			
Startup Time		ISO7886-2	ISO7886-2
Volumetric Accuracy (Manual Use, tolerance on graduated capacity)		ISO7886-1 and ISO 7886-2	ISO7886-1 and ISO 7886-2

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Sterility Product (N/A* for BNS)	ISO 11135 , ISO 11137 and PH Eur. 5.0	ISO 11135 , ISO 11137 and PH Eur. 5.0
Not Manufactured with BPA	Manufacturing process does not include BPA	Manufacturing process does not include BPA
Not made with natural rubber latex	Not made with natural rubber latex	Not made with natural rubber latex
Stopper Separation from plunger	ISO7886-1	ISO7886-1
Liquid leakage past stopper under pressure (back rib)	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Liquid leakage past stopper under pressure (front rib)	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Air Leakage past Stopper in aspiration	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Dead space	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Maximum Usable Capacity	ISO7886-1	ISO7886-1
Fiducial Line	ISO7886-1	ISO7886-1
Hard Height	ISO7886-2	ISO7886-2
Short-Term Flow Rate Accuracy (incl Stiction)	ISO 7886-2	ISO 7886-2
Overall Percentage Error	ISO7886-2	ISO7886-2
Max Variation in Flow Rate	ISO7886-2	ISO7886-2
Plunger Movement Forces (Pump)	ISO7886-2	ISO7886-2
Syringe Compliance	ISO7886-2	ISO7886-2
Uniform Stopper Appearance	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Scale - Graduation Line Intervals	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Scale - Unit of measure	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Scale Lines	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Scale Numbering	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2

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Scale Length	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Scale Position	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Marking – Syringe Barrel	ISO7886-1 and ISO7886-2	ISO7886-1 and ISO7886-2
Air leakage past stopper in aspiration (vacuum)	ISO7886-1	ISO 7886-1
Stopper separation from plunger	ISO7886-1	ISO 7886-1
Biocompatibility Testing:		
Cytotoxicity	ISO 10993-5, 10993-12 and USP <87>	ISO 10993-5, 10993-12 and USP <87>
Hemolysis	Per ISO 10993-4 and 10993-12	Per ISO 10993-4 and 10993-12
Acute Systemic Toxicity	Per ISO 10993-11 and 10993-12	Per ISO 10993-11 and 10993-12
Intracutaneous Reactivity	Per ISO 10993-10, 10993-12 USP and <88>	Per ISO 10993-10, 10993-12 USP and <88>
Sensitization	Per ISO 10993-10	Per ISO 10993-10
Pyrogenicity	Per ISO 10993-11, 10993-12 and USP 151	Per ISO 10993-11, 10993-12 and USP 151
Elastomeric Closures for Injections	USP <381>	USP <381>
ISO 7886-1: Acidity/Alkalinity and Extractable Metals	ISO 7886-1	ISO 7886-1
Extractables/Leachables Assessment	ISO 10993-17 and ISO 10993-18	ISO 10993-17 and ISO 10993-18
Particulate Matter	USP <788>	USP <788>
Endotoxin, LAL	USP <85>	USP <85>

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Non-Clinical Performance Data

BD has performed the following non-clinical/design verification testing, including shelf life testing and the results of these tests demonstrate that the BD Plastipak™ Syringe performed in an equivalent manner to the predicate devices. As there are no packaging changes occurring as part of this submission, all packaging data was leveraged from predicate devices. Labeling requirements were implemented for BNS sterilization instructions.

Syringe Performance	Startup Time	Subject device met the pre-established acceptance criteria per ISO7886-2.
	Volumetric Accuracy (Manual Use, tolerance on graduated capacity)	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Sterility Product (N/A* for BNS)	Subject device met the pre-established acceptance criteria per ISO 11135 , ISO 11137 and PH Eur. 5.0
	Stopper Separation from plunger	Subject device met the pre-established acceptance criteria per ISO7886-1.
	Liquid leakage past stopper under pressure (back rib)	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Liquid leakage past stopper under pressure (front rib)	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Air Leakage past Stopper in aspiration	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Dead space	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Maximum Usable Capacity	Subject device met the pre-established acceptance criteria per ISO7886-1.
	Fiducial Line	Subject device met the pre-established acceptance criteria per ISO7886-1
	Hard Height	Subject device met the pre-established acceptance criteria per ISO7886-2.

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Syringe Performance Test	Short-Term Flow Rate Accuracy (incl Stiction)	Subject device met the pre-established acceptance criteria per ISO7886-2.
	Overall Percentage Error	Subject device met the pre-established acceptance criteria per ISO7886-2.
	Max Variation in Flow Rate	Subject device met the pre-established acceptance criteria per ISO7886-2.
	Plunger Movement Forces (Pump)	Subject device met the pre-established acceptance criteria per ISO7886-2.
	Syringe Compliance	Subject device met the pre-established acceptance criteria per ISO7886-2.
	Uniform Stopper Appearance	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Scale - Graduation Line Intervals	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Scale - Unit of measure	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Scale Lines	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Scale Numbering	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Scale Length	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Scale Position	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Marking – Syringe Barrel	Subject device met the pre-established acceptance criteria per ISO7886-1 and ISO7886-2.
	Air leakage past stopper in aspiration (vacuum)	Subject device met the pre-established acceptance criteria per ISO7886-1
	Stopper separation from plunger	Subject device met the pre-established acceptance criteria per ISO7886-1

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Sterilization Test	Irradiation	Subject device met the pre-established acceptance criteria per ISO 11137-1 and ISO 11137-2
	Ethylene Oxide (Eto)	Subject device met the pre-established acceptance criteria per ISO 11135 and ISO 10993-7
Biocompatibility Test	Cytotoxicity	Per ISO 10993-5 and 10993-12, USP <87> Non-cytotoxic
	Hemolysis	Per ISO 10993-4 and 10993-12, Non-hemolytic
	Acute Systemic Toxicity	Per ISO 10993-11 and 10993-12, Non-toxic
	Intracutaneous Reactivity	Per ISO 10993-10 and 10993-12, USP <88> Non-Irritant
	Sensitization	Per ISO 10993-10, Non-Sensitizer
	Pyrogenicity	Per ISO 10993-11, 10993-12 and USP 151, Non-Pyrogenic
	Elastomeric Closures for Injections	USP <381> Met Type I and II closures
	ISO 7886-1: Acidity/Alkalinity and Extractable Metals	ISO 7886-1 Pass
	Extractables/Leachables Assessment	ISO 10993-17 and 18 Pass
	Particulate Matter	USP <788> Pass
	Endotoxin, LAL	USP <85> Pass

Clinical Testing
Clinical testing was not required for this submission.

Substantial Equivalence
The BD Plastipak™ Syringe is substantially equivalent to the predicate devices in intended use, operating principle, technology, design, materials and performance.

Conclusion
The BD Plastipak™ Syringe has been verified to meet the established performance criteria above. The results of the non-clinical/design verification testing demonstrate that the BD Plastipak™ Syringe perform as intended and perform as well as the legally marketed predicate devices for the same intended use. Therefore the devices are substantially equivalent.