October 23, 2018

Becton, Dickinson and Company
Victoria Morrow
Sr. Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K172670
Trade/Device Name: BD Single Use, Hypodermic Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 2, 2018
Received: February 5, 2018

Dear Victoria Morrow:

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,

Alan M. Stevens -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172670

Device Name
BD Single Use, Hypodermic Syringe

Indications for Use *(Describe)*
The BD Single Use, Hypodermic 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.

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510(k) Summary (21 CFR §807.92)

BD Single Use, Hypodermic Syringe

Submitter Information	Submitter Name: Submitter Address: Contact Person: Email Address: Phone Number: Fax Number: Date of Preparation:	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 Victoria Morrow Sr. Regulatory Affairs Specialist Victoria_morrow@bd.com Phone: (201) 847-6626 Fax: (201) 847-5307 October 23, 2018
Subject Device	Trade Name: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Single Use, Hypodermic Syringe Piston Syringe 21 CFR §880.5860 Piston Syringe Class II device FMF (Syringe, Piston) General Hospital
Predicate Device	Trade Name: 510(k) Reference: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Single Use, Hypodermic Syringe K980987 Piston Syringe 21 CFR §880.5860 Piston Syringe Class II device FMF (Syringe, Piston) General Hospital
Device Description	The BD Single Use, Hypodermic Syringe is a three-piece, sterile, single use hypodermic syringe with a 6% (Luer) male connector in 3ml, 5ml and 10ml Luer-Lok syringe sizes. The BD Single Use, Hypodermic 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 modified BD Single Use, Hypodermic Syringe includes a new resin material in the barrel of the syringe. The syringe performance characteristics are equivalent to the predicate device.	
Indications for Use	The BD Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.	
Technological Characteristics	The subject BD Single Use, Hypodermic Syringe, which uses a new polyproplyene barrel resin is equivalent to that of the predicate BD Single Use, Hypodermic Syringe in intended use, materials and performance characteristics.	

Element of Comparison		Subject Device	Predicate Device
Indications for Use/Intended Use		The BD Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.	The BD Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.
Syringe materials	Barrel	Polypropylene	Polypropylene
	Barrel Lubricant	Silicone	Silicone
	Plunger Rod	Polypropylene	Polypropylene
	Stopper	Polyisoprene Rubber	Polyisoprene Rubber
	Stopper Lubricant	Silicone	Silicone
Sterilization Method		Gamma Irradiation E-beam	Gamma Irradiation E-beam
SAL		10^{-6}	10^{-6}
Shelf Life		5 Years	5 Years

Performance Tests

BD has performed the following non-clinical/design verification testing based on the risk analysis conducted and the results of these tests demonstrate that the BD Single Use, Hypodermic Syringe performed in an equivalent manner to the predicate device.

- Break Out Force
- Sustaining Force
- Flange Bend Force
- Dimensional Stability of Barrel ID (inner diameter)
- Barrel Scale Permanency
- Barrel Impact Test
- ISO 7886 and ISO 594 Leakage Testing

The device is sterilized using a gamma irradiation process and was validated per ISO 11137-2:2013.

In addition, a biocompatibility evaluation was conducted on the subject device per ISO 10993-1:2009, Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process. Based on the evaluation, the following biological tests were conducted:

- Cytotoxicity (Per ISO 10993-5, Non-cytotoxic)
- Hemolysis (Per ISO 10993-4, Non-hemolytic
- Acute Systemic Toxicity (Per ISO 10993-11, Non-toxic)
- Intracutaneous Reactivity (Per ISO 10993-10, Non-Irritant)
- Sensitization (Per ISO 10993-10, Non-Sensitizer)
- Pyrogenicity (Per ISO 10993-11 and USP <151>, Non-Pyrogenic)
- Acidity/Alkalinity/ Extractable Metals (Per ISO 7886-1, met acceptance criteria)
- Chemical Extractables Analysis (Per ISO 10993-18, no toxicologically significant differences in extractables profiles.)

Per the design control requirements specified in 21 CFR 820.30, the subject device met all predetermined acceptance criteria for the above-listed performance tests, demonstrating substantial equivalence to the predicate device.

Clinical Testing	Clinical testing was not required for this submission
Summary of Substantial Equivalence	The BD Single Use, Hypodermic Syringe is substantially equivalent to the predicate device in intended use, principles of operation, technology, design, materials and performance.