DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 2, 2015

Becton, Dickinson and Company
Murtaza Rana
Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, NJ 07417

Re: K151766
Trade/Device Name: BD Single Use, Hypodermic Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: June 25, 2015
Received: June 30, 2015

Dear Murtaza Rana:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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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)*
K151766

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K151766

510(k) Summary

Submitted By: Murtaza Rana
Regulatory Affairs Specialist
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Phone: (201)847-6980
Fax: (201)847-5307

Date Prepared: August 3, 2015

Device:		
	Trade Name:	BD Single Use, Hypodermic Syringe
	Common Name:	Piston Syringe
	Classification:	Class II device, 21 CFR §880.5860, Piston Syringe
	Product Code:	FMF (Syringe, Piston)

Predicate Device: K980987
BD Single Use, Hypodermic Syringe

Device Description
The BD Single Use, Hypodermic Syringe is a three-piece, sterile, single use hypodermic syringe with a 6% (Luer) male connector in 1ml Luer Slip, 3ml, 5ml, 10ml and 20ml 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 plastic barrel with a graduated scale, a lubricated synthetic rubber stopper and a plastic plunger rod. The plunger rod is pulled along the inside of the barrel to aspirate fluids and pushed along the inside of the barrel 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 Single Use, Hypodermic Syringe are provided sterile (EtO) in a syringe only configuration or with a hypodermic needle. 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.

Intended 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 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	Rubber	Rubber
	Stopper Lubricant	Silicone	Silicone
Sterilization Method		Ethylene Oxide	Ethylene Oxide
SAL		10^{-6}	10^{-6}
Shelf Life		5 Years	5 Years

Non-Clinical Testing

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.

Performance Characteristic		Acceptance Criteria
Functional Testing	Break Out Force	Equivalence to Predicate
	Sustaining Force	Equivalence to Predicate
	Flange Bend Force	Equivalence to Predicate
	Dimensional Stability of Barrel ID (inner diameter)	Equivalence to Predicate
	Barrel Scale Permanency	Equivalence to Predicate
	Barrel Impact Test	Equivalence to Predicate
Biocompatibility Testing	Cytotoxicity	Per ISO10993-5, Non-toxic
	Hemolysis	Per ISO10993-4, Non-toxic
	Acute Systemic Toxicity	Per ISO10993-11, Non-toxic
	Intracutaneous Reactivity	Per ISO10993-10, Non-Irritant
	Sensitization	Per ISO10993-10, Non-Sensitizer
	Pyrogenicity	Per ISO 10993-11 and USP 151, Non-Pyrogenic
	Chemical Extractable Analysis	Per ISO 10993-18, acceptable level of extracts.

Clinical Testing
Clinical testing was not required for this submission.

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.

Conclusion
The BD Single Use, Hypodermic Syringe has been verified to meet the established performance criteria above. The results of the non-clinical/design verification testing demonstrate that the BD Single Use, Hypodermic Syringe performs as intended and performs as well as the legally marketed predicate device.