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

December 19, 2016

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

Re: K162081
Trade/Device Name: BD 1ml Luer-Lok™ Hypodermic Syringe
BD 1 mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle
BD 1ml Luer-Lok™ Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: November 17, 2016
Received: November 18, 2016

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" (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 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,

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)*
K162081

Device Name
BD 1mL Luer-Lok™ Hypodermic Syringe

Indications for Use *(Describe)*
The BD 1mL Luer-Lok™ 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.

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)*
K162081

Device Name
BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle

Indications for Use *(Describe)*
The BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle is intended for use by health care professionals for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin.

The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/ syringe combination.

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."

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)*
K162081

Device Name
BD 1mL Luer-Lok™ Insulin Syringe

Indications for Use *(Describe)*
The BD 1mL Luer-Lok™ Insulin Syringe is intended for subcutaneous injection of U-100 insulin.

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 – K162081

Submitted By:

Murtaza Rana
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Becton, Dickinson and Company
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Phone: (201)847-6980
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Date Prepared: December 15, 2016

Subject Devices:

Trade Name:	BD 1mL Luer-Lok™ Hypodermic Syringe
Common Name:	Piston Syringe
Classification:	Class II device, 21 CFR §880.5860, Piston Syringe
Product Code:	FMF (Syringe, Piston)
Trade Name:	BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle
Common Name:	Piston Syringe, Hypodermic Needle
Classification:	Class II, 21 CFR §880.5860, Piston Syringe
Product Code:	FMF (Syringe, Piston), FMI (Needle, Hypodermic, Single Lumen)
Trade Name:	BD 1mL Luer-Lok™ Insulin Syringe
Common Name:	Piston Syringe
Classification:	Class II device, 21 CFR §880.5860, Piston Syringe
Product Code:	FMF (Syringe, Piston)

Predicate Devices:

Trade Name:	BD 1mL Luer-Lok™ Hypodermic Syringe
510(k) Reference:	K941562
Common Name:	Piston Syringe
Classification:	Class II device, 21 CFR §880.5860, Piston Syringe
Product Code:	FMF (Syringe, Piston)
Trade Name:	BD Hypodermic Needle
510(k) Reference:	K021475
Common Name:	Hypodermic Needle
Classification:	Class II, 21 CFR §880.5570, Hypodermic Single Lumen Needle
Product Code:	FMI (Needle, Hypodermic, Single Lumen)
Trade Name:	BD Eclipse™ Hypodermic Needle
510(k) Reference:	K161170
Common Name:	Hypodermic Needle
Classification:	Class II, 21 CFR §880.5570, Hypodermic Single Lumen Needle
Product Code:	FMI (Needle, Hypodermic, Single Lumen)

Trade Name:	BD 1mL Luer-Lok™ Insulin Syringe
510(k) Reference:	K024112
Common Name:	Piston Syringe
Classification:	Class II device, 21 CFR §880.5860, Piston Syringe
Product Code:	FMF (Syringe, Piston)

Device Description

The BD 1mL Luer-Lok™ Hypodermic Syringe and BD 1mL Luer-Lok™ Insulin Syringe are three-piece sterile, single use, hypodermic syringes with male 6% (Luer) conical lock fittings, which are connectable to a compatible female 6% (Luer) connector. The syringe assemblies for both products are identical and consist of a lubricated styrene acrylic copolymer 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 barrel scale of the BD 1mL Luer-Lok™ Hypodermic Syringe incorporates a scale graduated in units of milliliters, while the barrel scale of the BD 1mL Luer-Lok™ Insulin Syringe incorporates a scale graduated in units of insulin.

The BD 1mL Luer-Lok™ Hypodermic Syringe is provided sterile by an irradiation sterilization method in a syringe only configuration or with a BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle.

The BD 1mL Luer-Lok™ Insulin Syringe is provided sterile by an irradiation sterilization method in a syringe only configuration.

The modified BD 1mL Luer-Lok™ Hypodermic Syringe, BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle and BD 1mL Luer-Lok™ Insulin Syringe include a change in the barrel resin material from a polycarbonate resin to a styrene acrylic copolymer resin. The syringe performance characteristics are equivalent to the predicate device.

Indications for Use/Intended Use

The **BD 1mL Luer-Lok™ Hypodermic Syringe** is intended for use by health care professionals for general purpose fluid aspiration/injection.

The **BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle** is intended for use by health care professionals for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin.

The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

The **BD 1mL Luer-Lok™ Insulin Syringe** is intended for subcutaneous injection of U-100 insulin.

Technological Characteristics
The subject BD 1mL Luer-Lok™ Hypodermic Syringe, BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle and BD 1mL Luer-Lok™ Insulin Syringe are equivalent to that of the predicate BD 1mL Luer-Lok™ Hypodermic Syringe, BD Hypodermic Needle, BD Eclipse™ Hypodermic Needle and BD 1mL Luer-Lok™ Insulin Syringe in intended use, materials and performance characteristics.

BD 1mL Luer-Lok™ Hypodermic Syringe:

Element of Comparison		Subject Device	Predicate Device
510(k) Reference:		K162081	K941562
Indications for Use/Intended Use		The BD 1mL Luer-Lok™ Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.	The BD 1mL Luer-Lok™ Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.
Syringe materials	Barrel	Styrene acrylic copolymer	Polycarbonate
	Barrel Lubricant	Silicone	Silicone
	Plunger Rod	Polypropylene	Polypropylene
	Stopper	Polyisoprene Rubber	Polyisoprene Rubber
	Stopper Lubricant	Silicone	Silicone
Sterilization Method		Gamma Irradiation	Gamma Irradiation
SAL		10^{-6}	10^{-6}
Shelf Life		5 Years	5 Years

BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle:

Element of Comparison		Subject Device	Predicate Device	Predicate Device	Predicate Device
510(k) Reference:		K162081	K941562	K021475	K161170
Indications for Use/Intended Use		The BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle is intended for use by health care professionals for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.	The BD 1mL Luer-Lok™ Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.	The BD Hypodermic Needle is intended for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin.	The BD Eclipse™ Hypodermic Needle is intended for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse Hypodermic Needle is compatible for use with standard luer-lock syringes. The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.
Syringe materials	Barrel	Styrene acrylic copolymer	Polycarbonate	N/A	N/A
	Barrel Lubricant	Silicone	Silicone	N/A	N/A
	Plunger Rod	Polypropylene	Polypropylene	N/A	N/A
	Stopper	Polyisoprene Rubber	Polyisoprene Rubber	N/A	N/A
	Stopper Lubricant	Silicone	Silicone	N/A	N/A

Element of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device
Needle Length	1/2 in. – 1 in.	N/A	1/2 in. – 1 in.	1/2 in. – 1 in.
Needle Gauge	20G – 30G	N/A	18G – 30G	18G – 30G
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	EtO
SAL	10^{-6}	10^{-6}	10^{-6}	10^{-6}
Shelf Life	5 Years	5 Years	5 Years	5 Years

BD 1mL Luer-Lok™ Insulin Syringe:

Element of Comparison		Subject Device	Predicate Device
510(k) Reference:		K162081	K024112
Indications for Use/Intended Use		The BD 1mL Luer-Lok™ Insulin Syringe is intended for subcutaneous injection of U-100 insulin.	The BD 1mL Luer-Lok™ Insulin Syringe is intended for subcutaneous injection of insulin.
Syringe materials	Barrel	Styrene acrylic copolymer	Polycarbonate
	Barrel Lubricant	Silicone	Silicone
	Plunger Rod	Polypropylene	Polypropylene
	Stopper	Polyisoprene Rubber	Polyisoprene Rubber
	Stopper Lubricant	Silicone	Silicone
Sterilization Method		Gamma Irradiation	Gamma Irradiation
SAL		10^{-6}	10^{-6}
Shelf Life		5 Years	5 Years

Non-Clinical Testing
BD has performed the following non-clinical/design verification testing and the results of these tests demonstrate that the BD 1mL Luer-Lok™ Hypodermic Syringe, BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle and BD 1mL Luer-Lok™ Insulin Syringe performed in an equivalent manner to the predicate devices.

Performance Characteristic		Acceptance Criteria
Functional Testing	Break Out Force	Equivalent to predicate
	Sustaining Force	Equivalent to predicate
	Dimensional Stability of Barrel ID (inner diameter)	Equivalent to predicate
	Strip/resistance to overriding	Equivalent to predicate
	Unscrewing torque	Equivalent to predicate
	Barrel Scale Permanency	Equivalent to predicate
	Sticktion	Equivalent to predicate
Biocompatibility Testing	Cytotoxicity	Per ISO 10993-5, Pass
	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
	Material-Mediated Pyrogenicity	Per ISO 10993-11 and USP 151, Non-Pyrogenic
	LAL Endotoxin	Per USP<85> and USP<161>, Pass
	Genotoxicity	Per ISO 10993-3, Non-mutagenic
	Subacute/Subchronic toxicity	Per ISO 10993-11, Non-toxic
	Chemical Extractable Analysis	Per ISO 10993-18, acceptable extractables/leachables profile
	Insulin compatibility (BD 1mL Luer-Lok™ Insulin Syringe only)	Pass

Clinical Testing
Clinical testing was not required for this submission.

Substantial Equivalence
The BD 1mL Luer-Lok™ Hypodermic Syringe, BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle and BD 1mL Luer-Lok™ Insulin Syringe are substantially equivalent to the predicate devices in intended use, operating principle, technology, design, materials and performance.

Conclusion
The BD 1mL Luer-Lok™ Hypodermic Syringe, BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle and BD 1mL Luer-Lok™ Insulin Syringe have been verified to meet the established performance criteria above. The results of the non-clinical/design verification testing demonstrate that the BD 1mL Luer-Lok™ Hypodermic Syringe, BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™ Hypodermic Needle and BD 1mL Luer-Lok™ Insulin Syringe perform as intended and perform as well as the legally marketed predicate devices and are therefore substantially equivalent.