October 21, 2019
Becton Dickinson and Company
Meriam Youssef
Senior Manager Regulatory Affairs
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K190054
Trade/Device Name: BD Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: September 19, 2019
Received: September 23, 2019

Dear Meriam Youssef:

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/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 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 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,

For CAPT Alan M. Stevens
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190054

Device Name
BD Insulin Syringe

Indications for Use *(Describe)*
Becton Dickinson insulin syringes are intended for subcutaneous injection of U-100 insulins

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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K190054 510(k) Summary

Submitted By: Meriam Youssef
Sr. Manager Regulatory Affairs, BD Medical- Diabetes Care
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 6557
Fax: 201 847 5307

Date Prepared: September 19, 2019

Device Name:

Trade Name:	BD Insulin Syringe™
Common Name:	Syringe, Piston
Regulation Name:	Piston syringe
Regulation:	21 CFR 880.5860
Product Code:	FMF

Legally marketed predicate device to which substantial equivalence is being claimed:

- BD Ultra-Fine™ Insulin Syringe, BD Ultra-Fine™ II Insulin Syringe, BD Insulin Syringes with the BD Ultra-Fine™ needle and BD Insulin Syringes with Micro-Fine™ IV Needle (K170386)

Device Description:

The subject BD Insulin Syringes are a plastic syringe designed for subcutaneous injection of a desired dose of U 100 insulin. The BD Insulin Syringe consists of a graduated barrel, plunger rod and needle/hub assembly. The BD Insulin Syringes are sterile, single use, and non-pyrogenic. These devices operate on the principles of a piston syringe. The BD Insulin Syringe with 6mm length cannula have a sub-brand name of BD Veo™ Insulin Syringe.

The BD Insulin Syringes are offered in the following sizes:

Syringe size (mL)	Bevel	Cannula length (mm)	Gauge (G)
0.3mL	3	12.7mm	29G
0.3mL	3	12.7mm	30G
0.3mL	3	8mm	29G
0.3mL	3	8mm	31G
0.3mL	3	6mm	31G
0.5mL	3	12.7mm	28G
0.5mL	3	12.7mm	29G
0.5mL	3	12.7mm	30G
0.5mL	3	8mm	31G
0.5mL	3	6mm	31G
1mL	3	16mm	27G
1mL	3	12.7mm	28G
1mL	3	12.7mm	29G
1mL	3	12.7mm	30G
1mL	3	8mm	30G
1mL	3	8mm	31G
1mL	3	6mm	31G
1mL	3	16mm	27G

Indications for Use:

Becton Dickinson insulin syringes are intended for subcutaneous injection of U-100 insulins.

Differences in Indications for use: The indications for use are the same as the predicate.

Substantial Equivalence Discussion:

General Information Feature	**Subject Device:** BD Insulin Syringe	**Predicate Device** BD Ultra-Fine™ Insulin Syringe, BD Ultra-Fine™ II Insulin Syringe, BD Insulin Syringes with the BD Ultra-Fine™ needle and BD Insulin Syringes with Micro-Fine™ IV Needle	**Comparison**
510(k) Number	K190054	K170386	N/A
Device Classification	Syringe Piston	Same	Same
Regulation Number	880.586	Same	Same
Product Code	FMF	Same	Same
Indications of Use	Becton Dickinson insulin syringes are intended for subcutaneous injection of **U 100** insulins	Becton Dickinson insulin syringes are intended for subcutaneous injection of **U-100** insulins.	Same
Specific Drug Use	U-100 Insulin	Same	Same
Capacity	1mL, 0.5mL, 0.3mL	1mL	The subject device includes a 0.5mL and 0.3ml model.
Bevel	3	3	Dimensional modifications to primary bevel of cannula
Cannula Gauge Size(s)	27G, 28G, 29G, 30G, 31G	27G, 28G, 29G, 30G, 31G	Same
Nozzle Tip Type	Snap fit needle hub for 0.3mL and 0.5mL designs for permanently attached needles Integral barrel for 1mL design for permanently attached needles	Integral barrel for 1mL design for permanently attached needles	Introduction of one glue well design for 1mL barrel configuration
Scale Markings	1 unit increments and ½ unit increments (0.3mL) 1 unit increments (0.5mL) 2 units increments (1mL)	2 units increments (1mL)	Addition of ½ unit scale mark increments

General Information Feature	**Subject Device:** BD Insulin Syringe	**Predicate Device** BD Ultra-Fine™ Insulin Syringe, BD Ultra-Fine™ II Insulin Syringe, BD Insulin Syringes with the BD Ultra-Fine™ needle and BD Insulin Syringes with Micro-Fine™ IV Needle	**Comparison**
Packaging Configuration	Polybag for self-contained syringe and blister pack (multiple blister packs per perforated sheet) offerings	Polybag for self-contained syringe and blister pack (individual blister pack) offerings	Addition of retention ring to 1mL self-contained insulin syringe Multiple blister packs per perforated sheet
Cannula Length Size(s)	6mm, 8mm, 12.7mm, 16mm	6mm, 8mm, 12.7mm, 16mm	Same
Cannula (Needle) material	304 Stainless Steel	304 Stainless Steel	Same
Cannula (Needle) shield material and Cap (for plunger rod) material	Polyethylene	Polyethylene	Modification to the co-monomer of polyethylene material
Cannula cover color	Orange	Orange	Same
Lubricant	Medical Grade Silicone	Medical Grade Silicone	Modification to lubricant formulation carrier solvent
Cannula bonding adhesive (UV cured)	UV Cured Adhesive	UV Cured Adhesive	New 0.3mL & 0.5mL UV Cured Adhesive
Scale marking ink	Solvent based Markem black colored ink	Solvent based Markem black colored ink	Same
Plunger rod material	Polystyrene	Polystyrene	Remove colorant additive from the plunger rod component
Plunger tip (stopper) material	Rubber stopper	Rubber stopper	Same
Barrel and Hub Material	Polypropylene	Polypropylene	New material formulation of polypropylene
Single Use Only	YES	YES	Same
Non-Pyrogenic	YES	YES	Same
Sterile (10^{-6})	YES	YES	Same

Discussion:

Apart from the above mentioned modifications to the design and materials, there are no technological differences between the subject and the predicate devices. The design modifications were assessed through performance testing per ISO 8537 and ISO 9626. The material changes were evaluated per ISO 10993-1.

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness.

Non-Clinical Testing:

Following BD's Quality System processes, required testing was conducted to validate the cumulative modifications made to the subject devices.

Substantial Equivalence is being supported with full performance testing representing the current BD Insulin Syringe devices currently marketed.

Bench functional performance

- Testing was conducted according to ISO 8537:2016 Sterile single-use syringes, with or without needle, for insulin, and ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices. This testing included Air Leakage, Cannula Pull Force, Cap Pull Force, Hub Pull Force, Liquid Leakage, Needle Break-Off Force, Penetration Force, Scale Print Permanency, Shield Pull Force, Syringe Filling Force, Syringe Injection Force (Force to Expel Water), Volumetric Accuracy, Dead Space and Corrosion Resistance.

Biocompatibility testing

- Testing was conducted according to relevant sections of ISO 10993:2019 Biological evaluation of medical devices. This testing included Cytotoxicity, Sensitization (GP Max), Sensitization, Intracutaneous Reactivity, Irritation, Acute Systemic Toxicity, Material Mediated Pyrogenicity, Subacute/Subchronic Toxicity, Hemocompatibility, and Genotoxicity (Bacterial and Mammalian). The medical device is classified as: externally communicating, blood path indirect, with prolonged contact duration.

Additional Testing:

ASTM F2148: 2013 Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA), ISO 11137-1:2006/Amd 2013(E) Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, ISO 11137-2:2013(E) Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose, ISO 11137-3: 2017(E) Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control, and ISO 11737-1:2018(E) Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products .

Results of testing demonstrated the BD Insulin Syringes met requirements for its intended use and is as safe and effective as its predicate device.

Clinical Testing:

Not Applicable

Conclusion:

The modifications to the design, dimensions, and materials of the subject device met the requirements of the standards. The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness.

The BD Insulin Syringes are substantially equivalent to the BD Ultra-Fine™ Insulin Syringe, BD Ultra-Fine™ II Insulin Syringe, BD Insulin Syringes with the BD Ultra-Fine™ needle and BD Insulin Syringes with Micro-Fine™ IV Needle cleared under K170386 with respect to the indications for use, target populations, treatment method, use environment and technological characteristics.