March 9, 2022

Becton, Dickinson and Company
Mark William
Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K212499
Trade/Device Name: BD Insulin Syringe (0.3mL)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 16, 2022
Received: February 17, 2022

Dear Mark William:

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,

CAPT Alan 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212499

Device Name
BD Insulin Syringe (0.3mL)

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.

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."

K212499 510(k) SUMMARY

Becton, Dickinson and Company

BD Insulin Syringe (0.3mL)

Submitted By: Mark William
Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 732-527-5008

Date Prepared: March 9, 2022

Device Name:		
	Trade Name:	BD Insulin Syringe (0.3mL)
	Common Name:	BD Insulin Syringes
	Classification:	Class II device; 21 CFR 880.5860, (Piston Syringe)
	Product Code:	FMF

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

- BD Insulin Syringe (K190054).

Device Description:

The BD Insulin Syringe, 0.3mL size, is a plastic syringe designed for subcutaneous injection of a desired dose of U-100 insulins. The product is a single use, sterile, non-toxic, non-pyrogenic, disposable syringe that consists of a needle, barrel, cannula shield, stopper, plunger, and plunger cap. The needle is a single ended lubricated stainless-steel cannula, which is permanently attached to the barrel nozzle with an adhesive. The needle is covered by a polyethylene cannula shield which is placed on the barrel. The barrel is molded from polypropylene with the exterior permanently marked with the proper scale markings. The stopper is attached to the plunger and a polyethylene cap is placed over the plunger rod. All products are gamma sterilized. The BD Insulin Syringe, 0.3mL size, are packaged in polybags as self-contained syringes. The subject device operates on the principle of a piston syringe and has a shelf life of 5 years. Table 1 below shows the different cannula configurations for BD Insulin Syringe (0.3mL).

Table 1: Summary of BD Insulin Syringe (0.3mL) Cannula Configurations

Gauge	Length	Bevel Size	Wall Type
29G	12.7mm	3	Regular Wall
30G	8mm		Thin Wall
30G	12.7mm		Thin Wall
31G	6mm		Thin Wall
31G	8mm		Thin Wall

The subject device includes the following main differences from the predicate device:

- Design changes:
  - New flared end design of the cannula shield
  - New integrated barrel tip design
- Material changes:
  - New cannula adhesive
  - New UV-bonded scale marking ink formulation
- Labeling changes:
  - Updates to include new ISO revisions and recommendations
  - Added cannula shield icon

Intended Use / Indications for Use

Characteristics	Subject Device BD Insulin Syringe (0.3mL) K212499	Predicate Device BD Insulin Syringes K190054
Indication for Use	BD Insulin Syringes are intended for subcutaneous injection of U-100 insulins.	BD Insulin Syringes are intended for subcutaneous injection of U-100 insulins.
Prescription Only or Over the counter	Over the counter	Over the counter

The indications for use statement for the subject device is identical to the predicate device.

Technological Characteristics

The technological characteristics of the BD Insulin Syringe (0.3mL) are similar to those of the predicate devices. A summary of the differences between BD Insulin Syringe (0.3mL) subject device and BD Insulin Syringes (0.3mL and 1mL) cleared under K190054 are outlined in Table 2 below.

Table 2: Comparison of Subject and predicate devices

General Information Feature	**Subject Device:** BD Insulin Syringe (0.3mL)	**Predicate Device:** BD Insulin Syringes	**Comparison**
Specific Drug Use	U-100 Insulins	U-100 Insulins	Same
Single Use Only	YES	YES	Same
Non-pyrogenic	YES	YES	Same
Sterilization method	Gamma irradiation	Gamma irradiation	Same
SAL 10^{-6}	YES	YES	Same
Capacity	0.3mL	0.3mL and 1mL	Different see Comment # 1
Cannula Gauge Size(s)	29G, 30G, and 31G	27G, 28G, 29G, 30G, and 31G	Same
Cannula Length Size(s)	6mm, 8mm, and 12.7mm	6mm, 8mm, 12.7mm, and 16mm	Same
Scale Markings	1 unit increments and ½ unit increments	1 unit increments and ½ unit increments (0.3mL) 2 units increments (1mL)	Same
Barrel Nozzle Tip	Unique integral barrel for permanently attached needles	Snap fit needle hub for permanently attached needles (0.3mL)	Different see Comment # 2

General Information Feature	**Subject Device:** BD Insulin Syringe (0.3mL)	**Predicate Device:** BD Insulin Syringes	**Comparison**
		Integral barrel for permanently attached needles (1mL)	
Cannula Shield Design	Flared cannula shield	Ribbed cannula shield (0.3mL) Flat head cannula shield (1mL)	Different see Comment # 3
Barrel Collar Inner Profile	Inner profile has added ribs	Inner profile has no ribs (0.3mL) Inner profile has ribs (1mL)	Different see Comment # 4
Materials			
Cannula	Stainless Steel 304	Stainless Steel 304	Same
Cannula Shield	Polyethylene	Polyethylene	Same
Cannula Shield Color	Orange	Orange	Same
Cannula Lubrication	Medical Grade Silicone	Medical Grade Silicone	Same
Cannula Bonding Adhesive	UV Cured Adhesive	UV Cured Adhesive	Different see Comment # 5
Cannula Hub	Integrated barrel design made with Polypropylene	Hub design made with Polypropylene (0.3mL) Integrated barrel design (1mL)	Different see Comment # 6
Scale Marking Ink	Black: UV-bonded ink	Black: Solvent based Markem	Different see Comment # 7

General Information Feature	**Subject Device:** BD Insulin Syringe (0.3mL)	**Predicate Device:** BD Insulin Syringes	**Comparison**
Plunger	Polystyrene	Polystyrene	Same
Plunger Stopper	Rubber stopper	Rubber stopper	Same
Plunger Stopper Lubricant	Medical Grade Silicone	Medical Grade Silicone	Same
Plunger Cap	Polyethylene	Polyethylene	Same
Plunger Cap Color	Natural or Orange	Natural or Orange	Same
Barrel	Polypropylene	Polypropylene	Same
Barrel Lubricant	Medical grade Silicone	Medical grade Silicone	Same
Labeling			
Editorial Changes	Copyright statement and website updated	Prior copyright statement and website	Different see Comment # 8
Updates as required by standards	ISO symbols updated	Prior ISO symbols	Different see Comment # 9
	Added Gauge size in millimeters in addition to inches	Gauge size displayed in inches	Different see Comment # 10
Image of proposed device	Cannula shield icon with the statement “Now with Wider Shield” added	No product/component icon on the labels	Different see Comment # 11
Content Change	IFU updated recommending straight in injection while pinching up skin	IFU recommended 45 degrees injection for longer needles with a pinch up	Different see Comment # 12

General Information Feature	Subject Device: BD Insulin Syringe (0.3mL)	Predicate Device: BD Insulin Syringes	Comparison
	Never re-shield and satisfaction guaranteed statements updated	Prior Never re-shield and satisfaction guaranteed statements	Different see Comment # 13
	Promotional insert removed and a new claim added to the shelf carton	Promotional insert	Different see Comment # 14

Comment 1: Minor dimensional changes to the barrel for the 0.3mL design with the same volumetric capacity per ISO 8537:2016.

Comment 2: Modification to introduce a new integral barrel tip design for manufacturing efficiency of the BD Insulin Syringe (0.3mL).

Comment 3: Wider cannula shield than the current BD Insulin Syringe designs for manufacturing efficiency.

Comment 4: Added ribs, for ease of manufacturing, no impact to the performance of the BD Insulin Syringe (0.3mL).

Comment 5: A new adhesive is introduced to mechanically hold the cannula in the barrel rather than adhere the cannula to the barrel.

Comment 6: Integrated barrel design replaces the hub design of the predicate. The barrel design is made with the same material as the predicate, Polypropylene.

Comment 7: The new UV-bonded ink formulation supports the new scale mark printing technology for ease of manufacturing.

Comment 8: Updated to current year.

Comment 9: Updated in accordance with ISO 8537and ISO 15223-1.

Comment 10: Updated in accordance with ISO 8537.

Comment 11: Added to highlight the modified subject device.

Comment 12: Updated to align with recent recommendations in published literature.

Comment 13: Updated for further clarity and simplification.

Comment 14: Claim substantiated by the American Diabetes Association Recommendations.

The modifications to the design, material, and labeling of the subject device met the requirements of the standards. The modifications between the predicate (K190054) and the subject device do not raise any new or different questions of safety or effectiveness.

Performance Testing:

The sterile single-use insulin syringes described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 9626 Second edition: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 8537 Third edition: Sterile single-use syringes, with or without needle, for insulin

Biocompatibility testing

In accordance with ISO 10993-1, the insulin syringe is classified as: Externally communicating medical device, direct contact with tissue; prolonged (>24 hours to 30 days) contact duration. The following testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic & Pyrogenicity
- Subacute/Subchronic Toxicity
- Genotoxicity

Particulate testing was conducted in accordance with USP <787> Subvisible Particulate Matter in Therapeutic Protein Injections and USP<790> Visible Particles in Injections and met the USP acceptance criteria.

Sterility, Shipping and Shelf-life

- The BD Insulin Syringe (0.3mL)'s sterilization method is gamma irradiation by Cobalt 60 with sterilization dose minimum of 20kGy.
- The subject device complies with the limits as stated in ISO 11137-2: Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose and ANSI/AAMI/ISO TIR13004:2013/(R)2016 for gamma irradiation sterilization. Residuals are not applicable for the gamma irradiation sterilization method.
- Limulus Amebocyte Lysate (LAL) assay was used to measure endotoxin limit the requirement was met. The product is non-Pyrogenic.
- Minimum Sterility Assurance Level of 10^{-6}.

- Sterile barrier testing performed on the subject device:
    - Microbial Ingress per analytical test procedures
    - Syringe Air Bubble Leak per analytical test procedures
- Packaging Integrity Testing under simulated shipping conditions were conducted to satisfy the requirements in ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems. All packaging deemed acceptable for protection of product and sterility maintenance.
- Accelerated stability testing has been conducted to validate the sterility and performance of the BD Insulin Syringe (0.3mL) device to support the shelf-life of 5 years.

Clinical Test Summary

Not Applicable.

Conclusions

The modifications to the design, material, and labeling of the subject device met the requirements of the standards. The modifications between the predicate (K190054) and the subject device do not raise any new or different questions of safety or effectiveness.

The BD Insulin Syringe (0.3mL) is substantially equivalent to the predicate BD Insulin Syringes (K190054) with respect to the indications for use, target populations, treatment method, use environment and technological characteristics.