January 25, 2021
Becton Dickinson and Company
Charlton Foo
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K203453
Trade/Device Name: BD Hypodermic Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: November 19, 2020
Received: November 23, 2020

Dear Charlton Foo:

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,

Rumi Young
Acting 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.

Submission Number *(if known)*

K203453

Device Name

BD Hypodermic Syringe

Indications for Use *(Describe)*

BD Hypodermic Syringe is intended for general aspiration and injection of fluids.

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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510(k) Summary

Submitted By: Charlton Foo
Staff Regulatory Affairs Specialist
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 6869
Fax: 201 847 5307

Date Prepared: January 21, 2021

Device Name:

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

Legally marketed predicate device to which substantial equivalence is being claimed:
K980580: Becton Dickinson Syringes

Reason for Submission:

- Expansion of syringe portfolio for general aspiration and injection of fluids in a 16mm needle length and thin wall configuration for the proposed syringe
- Material modifications
- Packaging Changes

Device Description:
The BD Hypodermic Syringe operates on the same fundamental scientific technology as the predicate cleared under K980580. The subject device consists of a: graduated barrel, plunger rod and needle/hub assembly. The device is offered with an attached 27G x 16mm cannula integrated with a 1mL syringe barrel capacity. The subject device is offered in self-contained (with a plunger cap) configuration. It is a single-use disposable device that is provided sterile. The BD Hypodermic Syringe is non-toxic and non-pyrogenic.

Intended Use:

BD Hypodermic Syringe is intended for general aspiration and injection of fluids.

The intended use of the subject device remains the **same** as the predicate device K980580 Becton Dickinson Syringes.

Comparison with Predicate Device:

The subject device has the same fundamental scientific technology as the predicate, which operate on the principles of a piston syringe. The modifications of the subject device consist of design, performance, and material. The purpose of this submission is to market the BD Hypodermic Syringe device. The table below provides a side-by-side comparison of the subject device compared to its predicate.

General Information Feature	Subject Device: BD Hypodermic Syringe	Predicate Device: Becton Dickinson Syringes (K980580)	Comparison
Classification	II	II	Same
Product Code	FMF	FMF	Same
Regulation Number	880.5860	880.5860	Same
Intended Use	BD Hypodermic Syringe is intended for general aspiration and injection of fluids.	These syringes are intended for general purpose fluid aspiration/ injection and insulin injection.	Same
Gauge	27G	28G, 27G, 26G	Same
Needle Length	16mm	12.7mm and 9.5mm	Addition of 16mm length
Needle wall thickness	Regular Wall and Thin Wall	Regular Wall	Addition of Thin Wall Configuration
Needle Shield Color	Gray	Gray (27G)	Same
Bevel	3 Bevel	3 Bevel	Same
Barrel Size	1mL	1mL and 0.5mL	Same
Maximum Dead Space	0.01mL	0.07mL	Reduction in maximum dead space
Scale Mark	Millimeters (mL)	Millimeters (mL)	Same
Single Use Only	Yes	Yes	Same

General Information Feature	Subject Device: BD Hypodermic Syringe	Predicate Device: Becton Dickinson Syringes (K980580)	Comparison
Packaging Configuration	Self-Contained configuration	Self-contained, Blister pack and Tray configuration	Same
Sterile (10^{-6})	Yes	Yes	Same
Sterilization Method	Gamma	Gamma	Same
Shelf Life	5 years	5 years	Same
Non-Pyrogenic	Yes	Yes	Same
Component Materials			
Needle	Stainless Steel	Stainless Steel	Same
Needle Shield	Polyethylene	Polyethylene / Polypropylene	Same
Needle Lubrication	Medical Grade Silicone	Medical Grade Silicone	Same
Plunger Rod	Polystyrene	Polypropylene	New plunger material
Plunger Tip	Polyisoprene Rubber and Styrene Butadiene Rubber	Polyisoprene Rubber	Additional stopper material
Plunger Cap	Polyethylene	Polyethylene	Same
Barrel	Polypropylene	Polypropylene	Same
Hub	Polypropylene	Polypropylene	Same

Testing:

Non-Clinical Test Summary

The subject device has similar technological characteristics as the predicate device cleared in K980580. BD has validated the design of the subject device as part of its design control process in accordance with the Quality System Regulation. This testing included functional performance per ISO 7886-1:2017, ISO 7864:2016, and ISO 9626:2016. Material changes were evaluated in accordance with ISO 10993-1:2018: Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.

Functional Performance Testing

- ISO 7886-1: 2017 - Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
- ISO 7864: 2016 - Sterile hypodermic needles for single use – Requirements and test methods

- ISO 9626: 2016 - Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods

Biocompatibility Testing

BD Hypodermic Syringe is categorized as an externally communicating device, involving direct contact with tissue for a prolonged contact duration (>24 hours to 30 days). A series of biological test were performed in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process with the following endpoints:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous reactivity
- Acute systemic toxicity
- Material mediated pyrogenicity
- Subacute/Subchronic toxicity
- Indirect hemolysis
- USP <788>

All material modifications met the requirements per ISO 10993-1:2018. Results of testing demonstrated the BD Hypodermic Syringe met requirements for its intended use and is as safe and effective as its predicate devices.

Clinical Test Summary

Not Applicable.

Conclusion:

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

The BD Hypodermic Syringe is substantially equivalent to the predicate device cleared under K980580 with respect to the indications for use, target populations, treatment method, use environment and technological characteristics.