July 15, 2020

Becton, Dickinson, and Company
Avital Merl
Director, Regulatory Affairs
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K201234
Trade/Device Name: BD SoloShot Mini Syringe/ BD Auto Disable Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: July 14, 2020
Received: July 15, 2020

Dear Avital Merl:

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 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

Indications for Use Statement

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 on last page

510(k) Number *(if known)*

Device Name
BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe

Indications for Use *(Describe)*
The BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe is intended for 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.
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510(k) SUMMARY

BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe

Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417

Phone: (201) 847-4739
Fax: (201) 847 5307

Contact Person: Avital Merl
Date Prepared: July 14,2020

Name of Device: BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe
Common or Usual Name: Piston Syringe
Classification Name: Piston Syringe; 21 CFR §880.5860
Regulatory Class: Class II device
Product Code: FMF

Predicate Device: BD SoloShot™ IX Syringe
510(k) Reference: K042934
Classification Name: Piston Syringe; 21 CFR §880.5860
Regulatory Class: Class II device
Product Code: FMF

Purpose of the Special 510(k) notice.

The BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe is a modification to BD SoloShot™ IX Syringe.

Intended Use

The BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe is intended for aspiration and injection of fluids.

Device Description

The BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe device is a sterile two-piece piston syringe designed to deliver a single fixed dose. It features a permanently attached hypodermic needle and auto-disable feature that prevents reuse of the syringe by locking the plunger rod in place after injection. The SoloShot™ Mini Syringe consists of a syringe barrel, a one-piece plunger rod (without rubber stopper), a clip affixed to the plunger rod and a integral needle. The needle is protected with a shield cover. The clip activates the auto-disabled feature, preventing re-use of the device. The syringe is individually blister packaged and ETO sterilized to SAL of 10^{-6} .

Technological Characteristics

Both the subject and predicate device operate as a piston syringe and are used for general purpose aspiration and injection of fluids. The system components and operational principle of the subject and predicate device are the same. The following technological differences exist between the subject and predicate devices:

- Dimensions of the barrel, plunger rod, clip, shield component, and packaging
- Minor material modifications to the scale mark ink and the barrel and shield resins.

A comparison of the subject and predicate device is summarized in the Table below.

	Subject Device: BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe	**Predicate Device: BD SoloShot™ IX Syringe**	**Comparison**
510(k) Number			
	K201234	K042934	
Intended Use			
	Intended for aspiration and injection of fluids.	Intended for aspiration and injection of fluids.	Same
Technological Characteristics			
Syringe Type	2 Piece (miniature size barrel and plunger)	2 Piece (barrel and plunger)	Different; Validated with Bench performance & Sterilization validation
Reuse Prevention (Safety) Feature	Auto-disabled (Miniature size), prevents syringe re-use	Auto-disabled, prevents syringe re-use	Different; Validated with Bench performance & Sterilization validation
Dose Saving Feature	Low Dead Space/Volume	Low Dead Space/Volume	Same
Integrated Needle	Yes	Yes	Same
Dose Setting/Volumes	Fixed doses: 0.5 mL	Fixed doses: 0.5 mL or 1.0 mL	Same
Needle Size (Gauge x Length)	23G X 1” 24G x 3/4” 25G x 1” 25G x 5/8”	22G X 1” 23G X 1” 24G X 3/4” 25G x 1” 25G x 5/8”	Same
Component Materials			
Barrel Material	Plastic	Plastic	Same; Minor modifications validated with Biocompatibility

Plunger Material	Plastic + Colorant (blue, violet, orange)	Plastic + Colorant (black, blue, violet, orange)	Same
Clip	Stainless steel	Stainless steel	Same
Integrated Cannula	Stainless Steel	Stainless Steel	Same
Shield	Plastic	Plastic	Same; Minor modifications validated with Biocompatibility
Biocompatibility			
Biocompatibility	Passed ISO 10993 testing; Non-pyrogenic, Non Toxic	Passed ISO 10993 testing; Non-pyrogenic, Non Toxic	Same
Sterilization	Ethylene Oxide (SAL 10^{-6})	Ethylene Oxide (SAL 10^{-6})	Same
Shelf Life	5 years	5 years	Same

Performance Data

BD performed the following bench, biocompatibility, and sterilization validation testing to support the modifications of the BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe. The results of these analyses demonstrate that the BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe performed in an equivalent manner to the predicate device.

- **Bench Performance**
  - Leakage, Dose Accuracy, Dead Space, Maximum Usable Capacity, Activation Forces, Cannula Pull Force, Shield Pull Force, Deactivation Volume/ Force to defeat the auto-destruct feature, Scale Mark Permanency, and Package Integrity
- **Material Biocompatibility Performance**
  - Cytotoxicity, Hemolysis, Acute Systemic Toxicity, Intracutaneous Reactivity, Sensitization, Pyrogenicity, Chemical Extractables Analysis, and Primary Dermal Irritation
- **Sterilization Performance**
  - Requalification of sterilization validation
- **Compliance to Standards**
  - ISO 10993-1: 2009/2018, ISO 11135: 2004, ISO 7886-3: 2005, ISO 7886-1:1993, ISO 7864:1993, ISO 9626:1991, ISO 6009:1992

In all instances, the BD SoloShot™ Mini Syringe functioned as intended and results observed met the predefined acceptance criteria.

Conclusion

The BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe is as safe and effective as the BD SoloShot™ IX Syringe. The BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe has the same intended uses and similar technological characteristics, and principles of operation as its predicate device. The technological differences between the BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe and its predicate device raise no new issues of safety or effectiveness. Bench, Biocompatibility, and Sterilization performance data demonstrate that the BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe is as safe and effective as the BD SoloShot™ IX Syringe. Thus, the BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe is substantially equivalent.