September 25, 2020

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

Re: K202446
Trade/Device Name: BD Preset™ Syringe & BD A-Line™ Syringe
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: August 25, 2020
Received: August 26, 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 and Part 809); 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,

Marianela Perez- Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
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)*
K202446

Device Name
BD Preset™ Syringe & BD A-Line™ Syringe

Indications for Use *(Describe)*
The BD Preset™ Syringe & BD A-Line™ Syringe are sterile, single use medical devices specifically intended to be used for the collection of whole blood specimens for the purpose of in vitro diagnostic testing which may include: pH, blood gases, electrolytes (including ionized calcium), metabolytes, co-oximetry. The device is intended to be used by trained healthcare professionals.

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

BD Preset™ Syringe & BD A-Line™ 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: September 24, 2020

510(k) Number: K202446

Name of Device: BD Preset™ Syringe & BD A-Line™ Syringe
Common or Usual Name: Blood Specimen Collection Device
Classification Name: Blood Specimen Collection Device; 21 CFR §862.1675
Regulatory Class: Class II device
Product Code: JKA

Predicate Device: BD Preset™ & BD A-Line™ Blood Collection Syringe
510(k) Reference: K022426
Classification Name: Blood Specimen Collection Device; 21 CFR §862.1675
Regulatory Class: Class II device
Product Code: JKA

Purpose of the Special 510(k) notice.

The BD Preset™ Syringe & BD A-Line™ Syringe is a modification to BD Preset™ & BD A-Line™ Blood Collection Syringe predicate device.

Intended Use

The BD Preset™ Syringe & BD A-Line™ Syringe are sterile, single use medical devices specifically intended to be used for the collection of whole blood specimens for the purpose of in vitro diagnostic testing which may include: pH, blood gases, electrolytes (including ionized calcium), metabolytes, co-oximetry. The device is intended to be used by trained healthcare professionals.

Device Description

The BD Preset™ Syringe & BD A-Line™ Syringe is a sterile, single use device designed to collect whole blood specimens for diagnostic testing. The BD A-Line™ Syringe is specifically designed for aspiration of blood samples from arterial lines. The BD Preset™ Syringe is offered with and without a pre-attached Eclipse™ needle and is specifically designed to be able to preset a desired volume but permits aspiration when necessary. It also includes a venting system that expels residual air through the self-venting membrane (as blood fills the syringe), which ensures rapid filling. The syringe is individually packaged, and Gamma sterilized with an SAL of 10^{-6}.

Technological Characteristics

Both the subject and predicate device are designed to collect whole blood specimens for diagnostic testing. 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:

- Material modifications to the device components
- Labeling revisions
- New pre-attached safety needle configuration offering

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

	SUBJECT DEVICE: **BD Preset™ Syringe & BD A-Line™ Syringe**	**PREDICATE DEVICE:** **BD Preset™ & BD A-Line™ Blood Collection Syringe**	**COMPARISON**
510(k) Submission			
	Pending	**K022426**	**N/A**
Indications for Use Statement			
	Sterile, single use medical devices specifically intended to be used for the collection of whole blood specimens for the purpose of in vitro diagnostic testing which may include: pH, blood gases, electrolytes (including ionized calcium), metabolytes, co-oximetry. The device is intended to be used by trained healthcare professionals.	intended to collect whole blood specimens for diagnostic testing which may include: pH, blood gases, electrolytes (including ionized calcium), metabolytes, co-oximetry, and other tests.	Same intended use; Minor clarifications
Technological Characteristics			
Syringe Components	Barrel, plunger with pre-attached stopper, and tip cap	Barrel, plunger with pre-attached stopper, and tip cap	Same
Configuration with Pre-attached Needle	Yes (safety needle)	Yes (non-safety needle)	Different. Bench, Biocompatibility, and Sterilization testing conducted to support change.
Syringe Volumes	3 mL	1 mL and 3 mL	Same
Needle Gauge Size	22-25G	22-25G	Same
Component Materials			
Barrel Material	Radiation grade polypropylene	Radiation grade polypropylene	Same.

	SUBJECT DEVICE: **BD Preset™ Syringe & BD A-Line™ Syringe**	PREDICATE DEVICE: **BD Preset™ & BD A-Line™ Blood Collection Syringe**	COMPARISON
Plunger Rod Material	Radiation grade polypropylene	Radiation grade polypropylene	Same.
Stopper Material (Pre-attached to plunger)	BD Preset™: Synthetic elastomer and venting media BD A-Line™: Synthetic elastomer	BD Preset™: synthetic elastomer and venting media BD A-Line™ synthetic elastomer	Same
Anticoagulant	Calcium balanced Lithium Heparin	Calcium balanced Lithium Heparin	Same
Barrel Printing	Black Ink	Black Ink	Same
Tip Cap	Polypropylene, Green colorant	Polypropylene (Translucent)	Different. Bench and Biocompatibility evaluations conducted to validate change.
Biocompatibility			
Biocompatibility	Passed ISO 10993 testing;	Passed ISO 10993 testing;	Same
Sterilization	Gamma (SAL 10^{-6})	Gamma (SAL 10^{-6})	Same
Shelf Life	2 years	2 years	Same

Performance Data

BD performed the following bench, biocompatibility, and sterilization validation testing to support the modifications of the BD Preset™ Syringe & BD A-Line™ Syringe. The results of these analyses demonstrate that the BD Preset™ Syringe & BD A-Line™ Syringe performed in an equivalent manner to the predicate device.

- **Bench Performance**
  - Tip cap leak, Shield Activation Force, Shield Unlocking Force, Shield Removal, Plunger Separation Force, Plunger Activation Force, Leak Past Stopper, Needle Cannula Pull Out Force, Ship and Leak, Heparin Activity
- **Material Biocompatibility Performance**
  - Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Material Mediated Pyrogenicity, Hemolysis, Color Migration, Extractables and Leachables
- **Sterilization Performance**
  - Requalification of sterilization validation
- **Compliance to Standards**
  - ISO 10993-1: 2009/2018, ISO 10993-4: 2017; ISO 10993-5: 2009, ISO 10993-10: 2010, ISO 10993-11: 2017, ISO 10993-18: 2020, USP 42-NF37:2019 <87>, USP 42-NF37:2019 <88>, USP 42-NF37:2019 <151>,ASTM F2148-18, ISO 11137-1: 2006, ISO 11137-2: 2013, ISO 11137-3: 2017, ISO 11737-1: 2018, ISO 11737-2: 2019, ASTM D4169-16, ISO 15223-1

In all instances, the BD Preset™ Syringe & BD A-Line™ Syringe functioned as intended and results demonstrated acceptable performance for the subject device.

Conclusion

The BD Preset™ Syringe & BD A-Line™ Syringe is as safe and effective as its predicate device. The BD Preset™ Syringe & BD A-Line™ Syringe has the same intended uses and similar technological characteristics, and principles of operation as its predicate device. The technological differences between the BD Preset™ Syringe & BD A-Line™ Syringe and its predicate device raise no new issues of safety or effectiveness. Bench, Biocompatibility, and Sterilization performance data demonstrate that the BD Preset™ Syringe & BD A-Line™ Syringe is as safe and effective as the predicate device. Thus, the BD Preset™ Syringe & BD A-Line™ Syringe is substantially equivalent to the predicate device.