April 15, 2026

Becton, Dickinson and Company
Sharanya Jangiti
Staff Regulatory Affairs Specialist
1 Becton Dr.
Franklin Lakes, NJ 07417

Re: K260128
Trade/Device Name: BD Preset™ and BD A-Line™ Arterial Blood Collection Syringes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: March 13, 2026
Received: March 16, 2026

Dear Sharanya Jangiti:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

PAULA V. CAPOSINO -S

Paula V. Caposino
Deputy Director
Division of Chemistry and
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OHT7: Office of In Vitro Diagnostics
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260128

Device Name
BD Preset™ and BD A-Line™ Arterial Blood Collection Syringes

Indications for Use *(Describe)*
The BD Preset™ and BD A-Line™ Arterial Blood Collection Syringes are sterile, single-use, in vitro diagnostic medical devices specifically intended to be used for the collection and containment of whole blood specimens for the purpose of in vitro diagnostic testing which may include: pH, blood gases, electrolytes (including ionized calcium), metabolites, 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) K260128 SUMMARY

Summary Preparation Date: December 15, 2025

Submitted by:

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Proprietary Names:

BD Preset™ and BD A-Line™ Arterial Blood Collection Syringes

Common or Usual Names:

Blood Specimen Collection Devices, CCCS (Critical Care Collection Syringes), ABG (Arterial Blood Gas), Critical Care Blood Collection Syringes, Arterial Blood Collection Syringes. Blood Gas Syringes

Regulatory Information

Classification Name: Blood specimen collection device
Classification Regulation: 21 CFR § 862.1675
Review Panel: Clinical Chemistry
Class: II
Product Code: JKA

Predicate Device:

BD Preset™ and BD A-Line™ Blood Collection Syringe (K022426)
510(k) Reference: K022426
Classification Name: Blood Specimen Collection Device; 21 CFR §862.1675

1mL BD Preset™ and BD A-Line™ Arterial Blood Collection Syringe Special 510(k) K260128
Specimen Management
Becton, Dickinson and Company

Regulatory Class: Class II device
Product Code: JKA

Purpose of the Special 510(k) notice.

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

Device Description

The BD Preset™ and BD A-Line™ Arterial Blood Collection Arterial Blood Collection Syringes are plastic needleless syringes with a graduated scale printed on the syringe barrel, with Luer Slip connection and a tip cap for sealing the syringe tip after specimen collection. The devices are spray coated on the inside of the syringe barrel with a calcium balanced lithium heparin solution that acts as an anticoagulant on whole blood specimens.

The BD Preset™ Arterial Blood Collection syringes are intended to be used in either preset or aspiration mode. The BD Preset™ Arterial Blood Collection syringes are designed for dual functionality, allowing use in either preset mode with an automatic venting system for filling to a desired volume or in manual aspiration mode like a traditional syringe. In contrast, BD A-Line™ Arterial Blood Collection Syringes are intended for manual aspiration mode.

The BD A-Line™ Arterial Blood Collection Syringe and BD Preset™ Arterial Blood Collection Syringe in the aspiration mode can be used for the collection of both venous and arterial specimens. Aspiration mode is a manual mode in which the user draws blood by pulling the plunger. The preset mode allows the user to preset the plunger, and the venting system within the plunger enables the blood to fill automatically, as arterial pressure pushes the blood to fill the syringe. The BD Preset™ Arterial Blood Collection Syringe in the preset mode is only assessed for collection of arterial specimens.

The subject devices in this premarket notification are the BD Preset™ and BD A-line™ Arterial Blood Collection Syringes, which have recommended draw volume of 0.6mL.

Indications for Use

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

Performance Standards:

- EN ISO 13485:2016+A11:2021 Medical devices quality management systems requirements for regulatory purposes
- EN ISO 14971:2019/A11:2021 Medical devices application of risk management to medical devices
- EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- EN ISO 18113-1: 2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (Labelling). Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
- EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer
- EN ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications-Connectors for intravascular or hypodermic applications
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 7886-1:2018 Sterile hypodermic syringes for single use – Part 1: Syringes for manual use. Note: Partial - The Standard is applicable for syringes that are used for both aspiration AND injection. ABG syringe are only indicated for aspiration use. Therefore, there are a number of Clauses/Requirements that do not apply for the ABG products.
- EN 62366-1:2015+A1:2020 Medical devices - Part 1: Application of usability engineering to medical devices
- EN ISO 11607-1:2020+A1:2023 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2020+A1:2023 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices
- EN ISO 11137-1:2015 /A2:2019 Sterilization of health care products - Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
- EN ISO 11137-2:2015+A1:2023 Sterilization of health care products - Radiation – Part 2: Establishing the sterilization dose
- EN ISO 11737-1:2018 /A1:2021 Sterilization of health care products – Microbiological methods - Part 1: Determination of a population of microorganisms on products
- EN ISO 11737-2:2020 Sterilization of health care products. Microbiological methods-Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

- EN ISO 10993-2:2022 Biological evaluation of medical devices – Part 2: Animal welfare requirements
- EN ISO 10993-4:2017 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
- EN ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2023 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- EN ISO 10993-11:2018 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- EN ISO 10993-12:2021 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
- EN ISO 10993-17:2009 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
- EN ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
- EN ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation

Substantial Equivalence

This Premarket Notification is for the BD Preset™ and BD A-Line™ Arterial Blood Collection Syringe which is substantially equivalent to the predicate given that it:

- Has the same intended use
- Uses the same operating principles
- Incorporates the same design
- Is manufactured from similar materials
- Is packaged using the similar sterile barrier and case materials
- Is provided sterile for single use and sterilized using the same method (irradiation) with the same sterility assurance level (SAL) of 10^{-6}
- Uses same scientific technology
- Has the same shelf life (2 years)

A detailed comparison of the subject device and the predicate device, including the indications for use, is provided in Table 1, Substantial Equivalence Comparison:

Table 1: Substantial Equivalence Comparison

Characteristic	Subject Device	Predicate Device	Comparison
Manufacturer	Becton, Dickinson and Company		Same
Device Name	BD Preset™ and BD A-Line™ Blood Collection Syringe		Same
510(k) No.	Pending	K022426	N/A
Regulation No.	21 CFR 862.1675		Same
Product Code	JKA		Same
Device Class	Class II		Same
Regulation Description	Blood Specimen Collection Device	Blood Specimen Collection Device	Same
Indications for Use	The BD Preset™ and BD A-Line™ Arterial Blood Collection Syringes are sterile, single-use, in vitro diagnostic medical devices specifically intended to be used for the collection and containment of whole blood specimens for the purpose of in vitro diagnostic testing which may include: pH, blood gases, electrolytes (including ionized calcium), metabolites, co-oximetry. The device is intended to be used by trained healthcare professionals.	The BD Preset™ and BD A-Line™ Blood Collection Syringes are 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 to improve readability and clarity, and to comply with IVDR regulations.
Technological Characteristics			
Syringe Components	Barrel, Plunger with pre-attached stopper and Tip Cap		Same
Syringe volumes	1mL		Same
Component Materials			
Barrel Material	Radiation grade polypropylene		Same. A catalyst manufacturing change was made by resin supplier. No change to final material.

Characteristic	Subject Device	Predicate Device	Comparison
Plunger Rod Material	BD A-Line™: Radiation grade polypropylene BD Preset™: Polystyrene		Same. A catalyst manufacturing change was made to the 1mL BD A-Line™ by resin supplier. No change to final material.
Plunger Stopper Material (Pre-attached to plunger)	BD Preset™: Plunger stopper Material is Buna-N (Nitrile) Rubber and Venting Media Material is Micro Media Thread BD A-Line™: polyisoprene stopper (7448/50 Black)	BD Preset™: Plunger stopper Material is Buna-N (Nitrile) Rubber and Venting Media Material is Micro Media Thread BD A-Line™: Styrene Butadiene rubber (SG020/J-02)	Same for BD Preset™. Different for BD A-Line™: Functional performance testing conducted on the 7448/50 (Black) stopper confirmed that the change does not impact overall product performance.
Anticoagulant	Calcium balanced Lithium Heparin		Same
Barrel Printing	Black Ink		Same
Tip Cap	Latex free Polyisoprene 7448/50	DP709 dry natural rubber	Different. Functional performance testing conducted on the new polyisoprene (7448/50 Black) stopper confirmed that the change does not impact the overall performance or functionality of the devices.
Population	Not intended to be used with any specific population.		Same
Condition of Use	Sterile, Single-use		Same
Sterilization Method	Gamma Irradiation		Same
Sterility Assurance Level	10^{-6}		Same
Shelf Life	2 years		Same
Biocompatibility	Compliant with ISO 10993 series		Same

Characteristic	Subject Device	Predicate Device	Comparison
Sterile Barrier	Each device is individually packed in a pouch. The Pouch is a sterile barrier		Same
Packaging	Primary Packaging: Plastic Tertiary Packaging: B Flute profile	Primary Packaging: Foil Tertiary Packaging: C Flute profile	Different. For the primary packaging change, ship and leakage testing was conducted. For the tertiary packaging change, ship testing was performed. Results confirmed that the changes do not impact the overall performance or functionality of the devices.

Performance Testing- Bench Summary

BD performed bench and biocompatibility testing to support the modifications of the BD Preset™ and BD A-Line™ Arterial Blood Collection Syringe. Results of testing demonstrate acceptable performance for the subject device and substantial equivalence to the predicate.

- Bench Performance: Tip Cap Leakage, Plunger Stopper Activation Force, Plunger Stopper Separation Force, Leakage Stopper Seal, Fit of Plunger Stopper, Ship and Air Leakage
- Biocompatibility Performance: Cytotoxicity, Hemocompatibility (Hemolysis), Irritation - Intracutaneous Reactivity, Sensitization, Acute Systemic Toxicity, Material Mediated Pyrogenicity, Extractables and Leachables

Performance Testing –Animal Summary

BD is not submitting any animal performance data in support of this 510(k) notice.

Performance Testing –Clinical Summary

BD is not submitting any clinical trial or study data in support of this 510(k) notice.

Conclusion:

In summary, the BD Preset™ and BD A-Line™ Arterial Blood Collection Syringe has the same intended use as its predicate device. Although there are differences between the BD Preset™ and BD A-Line™ Arterial Blood Collection Syringe and its predicate device, namely device component material modifications, packaging material modifications and labeling modifications,

these differences do not raise new questions of safety or efficacy. In addition, the subject device has been evaluated via non-clinical performance testing to demonstrate the device continues to perform as expected and is substantially equivalent to the predicate device.

Based on the comparison and analysis above and the performance testing conducted, the subject device is determined to be Substantially Equivalent (SE) to the predicate device.