March 21, 2025

Becton Dickinson and Company
Eva Zapletal Sawyer
Sr. Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K243649
Trade/Device Name: BD Vacutainer® Multiple Sample Luer Adapter
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: February 18, 2024
Received: February 19, 2025

Dear Eva Zapletal Sawyer:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 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 systems (QS) regulation (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,

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243649

Device Name

BD Vacutainer® Multiple Sample Luer Adapter

Indications for Use *(Describe)*

The BD Vacutainer® Multiple Sample Luer Adapter is a sterile, single-use, non-invasive medical device intended to be connected with BD Vacutainer® brand needle holders, to enable blood collection from venous access devices, such as needles and blood collection sets or catheters with female luer connectors into blood collection tubes or blood culture bottles for the purpose of in vitro diagnostic testing. These devices are intended to be used by 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.

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."

BD Vacutainer® Multiple Sample Luer Adapter Traditional 510(k)
Integrated Diagnostic Solutions
Becton, Dickinson and Company

510(K) SUMMARY - K243649

Summary Preparation Date: March 20, 2025

Submitted by:

Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885
Phone: (201) 847-6800

Contact:

Eva Zapletal Sawyer
Senior Regulatory Affairs Specialist
Email: Eva.Sawyer@bd.com
Work: (410) 372- 7244

Proprietary Names:

BD Vacutainer® Multiple Sample Luer Adapter

Common or Usual Names:

Blood Collection Tubes, Vials, Systems, Serum Separators

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 Vacutainer® Multiple Sample Luer Adapter (K991088)

Performance Standards:

- EN ISO 13485:2016+A11:2021 Medical devices quality management systems requirements for regulatory purposes
- EN ISO 14971:2019 Medical devices application of risk management to medical devices
- EN ISO15223-1:2021 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements

- EN ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications-Connectors for intravascular or hypodermic applications
- EN ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019 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
- ISO 11737-2:2019 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

Device Description

The BD Vacutainer® Multiple Sample Luer Adapter consists of a luer-slip fitting (male) which mates with the female Luer connector of venous access devices, and an NP (non-patient) cannula, which punctures the stopper of the evacuated tube(s), or the septum of a blood culture bottle(s) to collect blood.

The NP cannula of the device is lubricated and has a sleeve that recovers over the cannula to prevent leakage during blood collection in-between tubes and/or bottles.

Each end of the device is enclosed in a plastic shield, which join together to fully protect the device. A tamper evident label secures the two shields together and allows identification of whether the sterile barrier has been compromised.

The device consists of the following components:

- Non-patient (NP) Cannula
- Sleeve
- Luer Hub
- NP Shield
- IV Shield
- Epoxy

Note: the IV Shield is intended for maintaining sterility of the luer-slip of the device; there is no IV needle component.

Indications for Use

The BD Vacutainer® Multiple Sample Luer Adapter is a sterile, single-use, non-invasive medical device intended to be connected with BD Vacutainer® brand needle holders, to enable blood collection from venous access devices, such as needles and blood collection sets or

catheters with female luer connectors into blood collection tubes or blood culture bottles for the purpose of in vitro diagnostic testing. These devices are intended to be used by healthcare professionals.

The proposed and predicate device have the same basic indication for use, the collection of a blood sample from venous access devices. The clarification of compatible blood collection devices does not raise new questions of safety or effectiveness.

Substantial Equivalence

This Premarket Notification is for the BD Vacutainer® Multiple Sample Luer Adapter which is substantially equivalent to the predicate given that it:

- Has a similar intended use
- Incorporates similar design
- Is manufactured from similar materials
- Is similarly provided sterile for single use and with the same sterility assurance level of 10^{-6}
- Uses similar scientific technology and operating principles
- Has the same shelf life (3 years)

The subject and predicate device are substantially equivalent as described in Table 1.

Table 1. Substantial Equivalence Comparison

Characteristic	Subject Device	Predicate Device	Comparison
Manufacturer	Becton, Dickinson and Company		Same
Device Name	BD Vacutainer® Multiple Sample Luer Adapter		Same
510(k) No.	Pending	K991088	N/A
Regulation No.	21 CFR 862.1675		Same
Product Code	JKA		Same
Device Class	Class II		Same
Regulation Description	Blood Specimen Collection Device		Same
Indications for Use	The BD Vacutainer® Multiple Sample Luer Adapter is a sterile, single-use, non-invasive medical device intended to be connected with BD Vacutainer® brand needle holders, to enable blood collection from venous access devices, such as needles and blood collection sets or catheters with female luer connectors into blood collection tubes or blood culture bottles for the purpose of in vitro diagnostic testing. These devices are intended to be used by healthcare professionals.	The Vacutainer® Brand Luer Adapter is a sterile, non-invasive device used to connect venous access devices such as needles, blood collection sets, and infusion sets to blood collection tubes. They are also used in connection with non-needle devices for collection of blood from catheters. The Vacutainer® Brand Luer Adapter is sold by itself and as a component of other Vacutainer® Brand devices.	Different; clarification of compatible devices does not raise questions of safety or effectiveness.
Hub Material	Polystyrene (MIPS 0415)		Same
Cannula Material	Stainless Steel		Same
Non-Patient Sleeve Material	Isoprene Rubber (7403/45)		Same
IV Shield Material	Polypropylene (PF511)		Same
Non-Patient Shield Material	High Density Polyethylene with Hexane Resin (9018)	High Density Polyethylene	Different; No changes have been made to the base resin. Additive qualification did not raise any questions of safety or effectiveness.
Non-Patient Cannula Lubricant	Polydimethylsiloxane (PDMS) –Medical grade silicone		Same
Adhesive	Epoxy		Same

Characteristic	Subject Device	Predicate Device	Comparison
Population	Not intended to be used with any specific population.		Same
Nature of Body Contact	Intact Skin and Blood (Indirect Blood Path)		Same
Duration of Use	Transient (Less than 60 minutes)		Same
Condition of Use	Sterile, Single-use		Same
Sterilization Method	Gamma Irradiation	Ethylene Oxide	Different; the device is irradiated to obtain the same Sterility Assurance Level (10^{-6})
Sterility Assurance Level	10^{-6}		Same
Shelf Life	3 years		Same
Biocompatibility	Cytotoxicity, Skin sensitization, Intracutaneous Reactivity, Acute System Toxicity, pyrogenicity, hemocompatibility		Same
Packaging/Sterile Barrier	NP and IV Shield Caps joined at hub; sterility indicated by tamper-evident label		Same

Performance Testing—Bench Summary

Results of the following non-clinical performance, biocompatibility, and sterilization testing validate that the subject device performs as intended over the course of the product shelf life and demonstrates acceptable performance:

Non-clinical Performance Testing:

The non-clinical performance tests below were conducted to verify that the subject device met all design specifications and performance standards, and is substantially equivalent to the predicate device.

- Torque to Break
- NP Cannula Pull Test
- Spinout Test
- IV Shield Pull Force Test
- NP Sleeve Pull-off Force Test
- Tube Push Off Test
- Leakage by Pressure Decay Test
- Sub-Atmospheric Pressure Air Leakage Test
- Stress Cracking Test
- Resistance to Axial Separation Test
- Sterile Barrier Microbial Challenge Test

Biocompatibility Testing:

The subject device is classified as a surface medical device that comes in contact with intact skin for a limited (<24 hours) duration.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity or Irritation
- Material-mediated Pyrogenicity
- Acute Systemic Toxicity
- Hemocompatibility
- Leachables/Extractables

Sterilization Testing:

The subject device demonstrates conformity to the following sterilization standards:

- 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

- ISO 11737-2:2019 Sterilization of health care products. Microbiological methods-Tests of sterility performed in the definition, validation and maintenance of a sterilization process

- ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

- ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

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 subject BD Vacutainer® Multiple Sample Luer Adapter described in this submission has the same intended use, technological characteristics, and principles of operation as the predicate device. The differences in sterilization method and non-patient shield material do not raise new or different questions of safety and effectiveness. 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.