July 3, 2025

Becton Dickinson and Company
Sravan Rajamani
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K243207
Trade/Device Name: BD Vacutainer® Eclipse™ Blood Collection Needle
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: June 2, 2025
Received: June 2, 2025

Dear Sravan Rajamani:

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 -S

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
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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)*
K243207

Device Name
BD Vacutainer® Eclipse™ Blood Collection Needle

Indications for Use *(Describe)*
The BD Vacutainer® Eclipse™ Blood Collection Needle is a sterile, single-use, medical device specifically intended to be used by healthcare professionals experienced with venipuncture on adults and children in accordance with the instructions for use for the collection of multiple venous blood samples into evacuated blood collection tubes, for the purpose of in vitro diagnostic testing. The needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide protection from accidental needlesticks.

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.

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K243207 - 510(k) Summary

BD Vacutainer® Eclipse™ Blood Collection Needle

Summary Preparation Date: July 3, 2025

Submitted by:
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Proprietary Names: BD Vacutainer® Eclipse™ Blood Collection Needle (K243207)

Common or Usual Names: Blood Collection Needle

Regulatory Information
Classification Name: Blood Collection Set
Classification Regulation: 21 CFR §862.6175
Regulatory Class: Class II
Product Code: JKA
Classification Panel: Clinical Chemistry

Predicate Device: BD Vacutainer® Push Button Blood Collection Set (K220212)
Classification Name: Blood Collection Set
Classification Regulation: 21 CFR §862.6175
Regulatory Class: Class II
Product Code: JKA
Secondary Product Code: FPA
Classification Panel: Clinical Chemistry

Indications for Use

The BD Vacutainer® Eclipse™ Blood Collection Needle is a sterile, single-use, medical device specifically intended to be used by healthcare professionals experienced with venipuncture on adults and children in accordance with the instructions for use for the collection of multiple venous blood samples into evacuated blood collection tubes, for the purpose of in vitro diagnostic testing. The needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide protection from accidental needlesticks.

Device Description

The BD Vacutainer® Eclipse™ Blood Collection Needle includes a one-piece double-ended needle/cannula fixed to a plastic hub. One end of the cannula is the intravenous (IV) end, and the other is the non-patient (NP) end covered with a sleeve. The whole device is encased in two plastic covers; one at each end of the cannula to protect the device, with a tamper-evident seal placed around the plastic covers. The protective cover/cap is provided to prevent damage and maintain the needle sterility before the point of use. A safety shield is connected to a hinge on a collar attached to the hub. The safety shield is manually activated by locking over the needle after removal from the vein, providing protection from accidental needlestick injuries.

The BD Vacutainer® Eclipse™ BCN consists of:

- Double-ended hollow stainless-steel cannula
- Threaded polystyrene hub
- Polystyrene collar
- Protective needle sleeve that interrupts blood flow between filling multiple tubes
- Safety shield that can be activated to cover the needle immediately after venipuncture to protect against accidental needle sticks during normal handling and disposal
- Pre-attached holder (for user convenience in some models)

The BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder (PAH) consists of a BD Vacutainer® Eclipse™ Blood Collection Needle threaded and bonded to a BD Vacutainer® One Use Holder. The Eclipse™ BCN with PAH allows for the immediate use of the product without the need for assembling the two components. This provides increased convenience to the user and is designed to help minimize the exposure of the user to the non-patient (NP) end of the needle.

Substantial Equivalence[1] The subject and predicate device are substantially equivalent as described in Table 1 below.

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[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended, and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Table 1: Substantial Equivalence Comparison

Characteristic	Subject Device BD Vacutainer® Eclipse™ Blood Collection Needle K243207	Predicate Device BD Vacutainer® Push Button Blood Collection Set K220212	Comparison
Intended Use/ Indications for use	The BD Vacutainer® Eclipse™ Blood Collection Needle is a sterile, single-use, medical device specifically intended to be used by healthcare professionals experienced with venipuncture on adults and children in accordance with the instructions for use for the collection of multiple venous blood samples into evacuated blood collection tubes, for the purpose of in vitro diagnostic testing. The needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide protection from accidental needlesticks.	The BD Vacutainer® Push Button Blood Collection Set is a sterile, multi-sample, single-use fixed winged blood collection set intended for use in the general population by healthcare professionals experienced with venipuncture to obtain blood specimens from patients, including those patients with difficult vein access who may have small, fragile, and/or non-palpable veins, into evacuated blood collection tubes and/or blood culture bottles. When used without the male Luer adapter, the device allows the clinician to obtain a blood specimen from the female Luer connector with a syringe, if necessary. The device can be used by healthcare professionals with infusion experience for short-term, single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and is to remain under the direct supervision of a clinician. The recommended use of the device is to activate the needle safety feature prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury.	Different; both the subject and predicate devices are intended for blood collection used by healthcare professionals; the predicate device has an additional indication for use for infusion (FPA). This difference does not raise new questions of safety or effectiveness.
Product Code	JKA	JKA, FPA	Different; the predicate device has an additional indication used for infusion (FPA). This difference does not raise new questions of safety or effectiveness.
Sterility	Gamma Irradiation to Sterility Assurance Level (SAL) of 10^{-6}		Same
Shelf Life	5 years (Eclipse™ BCN); 3 years (Eclipse™ Pre-Attached)	2 years	Different; the difference in shelf life does not raise new questions of safety or effectiveness as demonstrated by shelf life testing.
Single Use	Yes		Same

Needle Wall Thickness	Thin Wall (TW)	Thin Wall (TW)	Same The dimensions and performance of the subject and predicate devices are compliant to ISO 9626.
Needle Geometry	3-bevel		Same
Needle Orientation	Bevel up		Same
Needle Configuration	1 ¼ in One-piece needle	3/4 in Two-piece needle	Different; the difference where the IV and NP cannulas are separate components in the predicate device do not raise new questions of safety or effectiveness.
Needle Gauge	21G, 22G	21G, 23G, 25G	Different; the difference in gauge sizes do not raise new questions of safety or effectiveness, as the proposed device sizes are within range of the size availability of the predicate.

Characteristic	**Subject Device** **BD Vacutainer® Eclipse™ Blood Collection Needle** **K243207**	**Predicate Device** **BD Vacutainer® Push Button Blood Collection Set** **K220212**	**Comparison**
Integrated Safety Feature?	Yes		Same
Safety Feature Design	Pivot Safety Shield	Retractable Needle (spring activated)	Different; both safety features comply with ISO 23908 and do not raise new questions of safety or effectiveness.
Safety Feature Activation Method	One-handed safety activation after venipuncture		Same
Integrated Needle Holder (Pre-attached holder)	Pre-attached models available; Non-Pre-Attached models are supplied without a holder		Same
Biocompatibility	ISO 10993 Series In vitro toxicity, Skin sensitization, Intracutaneous Reactivity, Acute System Toxicity, Hemocompatibility		Same
Packaging/ Sterile Barrier (	Non-pre-attached: IV and NP needle end caps/shields joined to collar with tamper-evident label; Pre-attached: blister package	Blister package	Same

Component Materials			
Cannula	Stainless steel 304		Same
Cannula Adhesive	Heat cured adhesive	UV cured adhseive	Different; the difference in how the adhesive is cured does not raise new questions of safety or effectiveness as demonstrated by ISO 10993 testing.
IV Shield/ Protector	IV Shield - Polypropylene	IV Protector - Polyethylene	Different; difference in material selection, component is a cannula cover to protect the needle point only, difference does not raise new questions of safety or effectiveness.
NP Shield	Polyethylene (non pre-attached model only)	n/a	Different;This difference does not raise new questions of safety or effectiveness.
NP Sleeve	Synthetic Isoprene Rubber (not made with natural rubber latex)		Same
NP End Lubricant	Silicone		Same
IV End Lubricant	Silicone		Same
Frictional Interface (for needle hub threads)	UV cured adhesive (non-Pre-Attached model only)	n/a	Different; does not raise new questions of safety or effectiveness as demonstrated by ISO 10993 testing.
Characteristic	**Subject Device** **BD Vacutainer® Eclipse™ Blood Collection Needle** **K243207**	**Predicate Device** **BD Vacutainer® Push Button Blood Collection Set** **K220212**	**Comparison**
Hub-Holder adhesive	UV cured adhesive used for pre-attached models only		Same
Collar	Polystyrene	n/a	Different; the collar is intended to pivot the safety shield, this difference does not raise new questions of safety or effectiveness.
Needle Hub	Polystyrene	Polycarbonate	Different; this difference in resins does not raise new questions of safety or effectiveness as demonstrated by ISO 10993 testing.
Safety Shield	Polypropylene	n/a	Different; the predicate device has a retractable needle safety feature, both the predicate and subject

			device comply with ISO 23908.
Holder	Non-Pre-Attached model: N/A (health care professional must obtain and attach compatible holder) Pre-Attached model: Polypropylene		Same
Non-pyrogenic	Yes		Same
Provided Sterile?	Yes		Same
Models/ SKUs	368607 368608 368609 368610 368650 368651	**367323** **367324** **367326** **367335** **367336** **367338** **367341** **367342** **367344** **367352** **367354** **367355** **368656** **368657** **368658** **368659**	Different models to distinguish different gauge size and device configurations, this difference does not raise new questions of safety or effectiveness

Performance Standards:

- AAMI/ANSI/ ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-2:2006 Biological evaluation of medical devices - Part 2: Animal welfare requirements
- ANSI AAMI ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- ANSI AAMI ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-9:2009 Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products
- ANSI AAMI ISO10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

- ANSI AAMI ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ANSI AAMI ISO 10993-13:2010 Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices
- ISO 10993-15:2019 Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys
- ANSI AAMI ISO10993-17:2009 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation
- 556-1:2001/AC:2006 Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
- ANSI AAMI ISO11137-1:2015/A2:2019 Sterilization of health care products -Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-1:2006/AMD 2:2018)
- ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ISO 11737-1:2018 AMD 2021 Sterilization of health care products -Microbiological methods - Part 1: Determination of a population of microorganisms on products
- ISO 11737-2:2020 Sterilization of medical devices – Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 23908:2013 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ANSI AAMI ISO11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ANSI AAMI ISO11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

Biocompatibility

The BD Vacutainer® Eclipse™ Blood Collection Needle follows the requirements of ISO 10993-1 and FDA Guidance: Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process". The device categorization is driven by the needle/cannula which is the only component that has direct contact with blood and therefore, the device categorization is the following "externally communicating medical device (circulating blood) with limited (≤ 24h) contact)".

Per FDA Guidance: Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process, biocompatibility testing conducted for the device categorization: Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-mediated Pyrogenicity and Hemocompatibility.

Non-Clinical Performance Summary

The non-clinical performance tests below were conducted to verify that the proposed devices met all design specifications and performance standards and are each Substantially Equivalent (SE) to the predicate device:

- Cannula-Hub Axial Pull Force
- Safety Shield Engagement
- Safety Shield Override
- Cantilever Force to Break Hub
- Sleeve Function
- Torque to Break Hub
- Torque to Unseat Holder
- Holder Spinout from Needle Hub
- IV and NP Shield Pull Force
- IV and NP Label Torque
- Sterile Barrier Performance
- Sharps Injury Protection Feature/ ISO 23908– Simulated Use testing
- ISO 9626 - Stainless Steel Needle Tubing testing

Results of non-clinical performance testing conducted to validate that the subject device performs as intended over the course of the product shelf life have demonstrated acceptable performance for the subject device.

In addition, the subject device is compliant with FDA’s Guidance document, Medical Devices with Sharps Injury Prevention Features (August 2005).

Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The BD Vacutainer® Eclipse™ Blood Collection Needle is substantially equivalent to BD Vacutainer® Push Button Blood Collection Set.