November 1, 2024

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

Re: K242320
Trade/Device Name: BD Vacutainer® One Use Holder
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: August 5, 2024
Received: August 5, 2024

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, 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
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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)*
K242320

Device Name
BD Vacutainer® One Use Holder

Indications for Use *(Describe)*
The BD Vacutainer® One Use Holder is a single-use, non-sterile device used by healthcare professionals to attach and hold a BD Vacutainer® brand venous access device such as a blood collection needle, a blood collection set, or a luer adapter during venipuncture connected to a BD Vacutainer® blood collection tube(s). This device may also be used with a BD Vacutainer® blood collection set with a luer adapter to obtain blood samples into a BD BACTEC™ blood culture bottle.

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.

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K242320- 510(K) SUMMARY

Summary Preparation Date:

November 1, 2024

Submitted by:

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Device Name: BD Vacutainer® One Use Holder

Trade/ Common name: Blood specimen collection device

Regulatory Information
Classification Name: Blood specimen collection device
Classification Regulation: 21 CFR §862.1675
Regulatory Class: Class II
Product Code: JKA

Predicate Device(s)

Greiner Vacuette® Blood Culture Holder (K122687)

Device Description

The BD Vacutainer® One Use Holder is a non-sterile, single-use plastic device used during the blood collection process. It consists of a one piece plastic barrel with a female threaded connector at one end into which the non-patient end of the hub of a BD Vacutainer® blood collection device is screwed. The other end is open for the insertion of a BD Vacutainer® evacuated blood collection tube or BD BACTEC™ Blood Culture Bottle This end also has flanges, which are intended to assist tube insertion. BD Vacutainer® One Use Holder is used to attach and hold a BD Vacutainer® Brand venous access device such as a blood collection needle, blood collection set or Multiple Sample Luer Adapter during venipuncture and to connect the subject device to a BD Vacutainer® blood collection tube or BD BACTEC™ blood culture bottle.

Indications for Use

The BD Vacutainer® One Use Holder is a single-use, non-sterile device used by healthcare professionals to attach and hold a BD Vacutainer® brand venous access device such as a blood collection needle, a blood collection set, or a luer adapter during venipuncture connected to a BD Vacutainer® blood collection tube(s). This device may also be used with a BD Vacutainer® blood collection set with a luer adapter to obtain blood samples into a BD BACTEC™ blood culture bottle.

Substantial Equivalence

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

Table 1: Substantial Equivalence Comparison

Characteristic	Subject Device	Predicate Device	Comparison
Indications for Use	The BD Vacutainer® One Use Holder is a single-use, non-sterile device used by healthcare professionals to attach and hold a BD Vacutainer® brand venous access device such as a blood collection needle, a blood collection set, or a luer adapter during venipuncture connected to a BD Vacutainer® blood collection tube(s). This device may also be used with a BD Vacutainer® blood collection set with a luer adapter to obtain blood samples into a BD BACTEC™ blood culture bottle.	The Blood Culture Holder is used to fill blood into blood culture bottles and tubes in routine venipuncture procedures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions. The SAFETY Blood Collection Set and/or Blood Collection Set + Blood Culture Holder are used in routine venipuncture procedures. The winged needle of the SAFETY Blood Collection Set is designed with a safety shield, which can be activated to cover the needle immediately following blood collection to aid in the protection against accidental needlestick	Similar; both devices are intended to be used with a venous access device to fill blood collection tubes and blood culture bottles. The subject device requires the healthcare worker to obtain and attach a blood collection needle, blood collection set, or luer adapter prior to venipuncture.

Characteristic	Subject Device	Predicate Device	Comparison
		injury. The Blood Culture Holder is used to fill blood into blood culture bottles and tubes.	The predicate device being supplied pre-attached to a needle does not raise any new or different questions of safety or effectiveness.
Population	All patient population	All patient population	Same
Design	The **cylindrical**-shaped holder is translucent to check the filling status of the blood collection tube. It consists of a **plastic** barrel with a female threaded connector at one end into which the hub of the BD Vacutainer® blood collection device is screwed. The other end has flanges to assist in gripping the device during use and is open to allow the passage of a BD Vacutainer® evacuated blood collection tube or BD BACTEC™ blood culture bottle.	**Cylindrical** translucent holder for vacuum bottle and tube placement: cylinder with threads which are compatible with male luer adapters. The design of the holders allows collection of blood into blood culture bottles and blood collection tubes.	Different; Both devices are cylindrical-shaped, used in blood collection tube or blood culture bottle placement during venipuncture for blood collection, and are compatible with male luer adapters. While, there are differences in device design and dimensions, performance testing of the subject device over the shelf life demonstrates the difference does not raise new or different questions of safety and effectiveness.
Condition of Use	Non-sterile, Single-Use	Non-sterile, Single-Use	Same
Shelf Life	5 years	5 years	Same
Sterility	Non-Sterile	Non-Sterile	Same
Material	Polypropylene / Clear	Polypropylene / Clear	Same
Tube/ Bottle Compatibility	13mm & 16mm blood collection tubes & blood culture bottles	13mm & 16mm blood collection tubes & blood culture bottles	Same
Needle Compatibility	Blood collection needle, blood collection set or Multi Sample Luer Adapter	Blood collection needle, blood collection set or luer adapter	Same

BD believes the characteristics, including the indications for use and design features, of the subject and the predicate devices are substantially equivalent.

Applied Standards:

- *ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements.*

Non-clinical Performance Summary

Non-clinical performance tests 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.

Clinical Data - Not Applicable.

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®One Use Holder is substantially equivalent to Greiner Vacuette ®Blood Culture Holder with respect to the indications for use, target population, and technological characteristics.