March 10, 2023

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

Re: K222478
Trade/Device Name: BD Vacutainer® Luer-Lok™ Access Device, BD Vacutainer® Blood Transfer Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: December 9, 2022
Received: December 12, 2022

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 (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); 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,

David Wolloscheck, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222478

Device Name
BD Vacutainer® Luer-Lok™ Access Device, BD Vacutainer® Blood Transfer Device

Indications for Use *(Describe)*

BD Vacutainer® Luer-Lok™ Access Device:
The BD Vacutainer® Luer-Lok™ Access Device is a sterile, single-use, noninvasive device intended to be used by healthcare professionals for safe, closed-system venous blood collection from a female Luer of a catheter port or blood collection set, directly into an evacuated blood collection tube(s) for in vitro diagnostic testing. This device may also be used with a blood collection set with a female Luer to collect blood cultures.

BD Vacutainer® Blood Transfer Device:
The BD Vacutainer® Blood Transfer Device is a sterile, single use, noninvasive medical device intended to be used by healthcare professionals for the safe, closed-system, needleless transfer of venous blood from a BD Luer-Lok™ tip syringe into evacuated blood collection tube(s) or blood culture bottle(s) for in vitro diagnostic testing.

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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K222478 - 510(K) SUMMARY

Summary Preparation Date

03/10/2023

Submitted by:

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Contact:

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Proprietary Names:

BD Vacutainer® Luer-Lok™ Access Device
BD Vacutainer® Blood Transfer Device

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(s)

Luer Access Device-holder with Preattached Multiple Sample Adapter (K200027)

Device Description

The BD Vacutainer® Luer-Lok™ Access Device and the BD Vacutainer® Blood Transfer Device are sterile, single use, non-invasive devices for the safe transfer of blood into an evacuated BD Vacutainer® blood collection tube or BD BACTEC™ blood culture bottle for in vitro diagnostic testing. The only difference between the devices is the BD Vacutainer® Luer-Lok™ Access device features a male Luer lock connection for connection with compatible female Luer catheter port (blood collection set) and the BD Vacutainer® Blood Transfer Device features a female Luer lock for connection with BD Luer-Lok™ syringes.

Table 1: Indications for Use

Proposed Device BD Vacutainer® Luer-Lok™ Access Device	**Proposed Device BD Vacutainer® Blood Transfer Device**	**K200027 Luer Access Device-holder with preattached multiple sample adapter**
The BD Vacutainer® Luer-Lok™ Access Device is a sterile, single-use, noninvasive device intended to be used by healthcare professionals for safe, closed-system venous blood collection from a female Luer of a catheter port or blood collection set, directly into an evacuated blood collection tube(s) for in vitro diagnostic testing. This device may also be used with a blood collection set with a female Luer to collect blood cultures.	The BD Vacutainer® Blood Transfer Device is a sterile, single use, noninvasive medical device intended to be used by healthcare professionals for the safe, closed-system, needleless transfer of venous blood from a BD Luer-Lok™ tip syringe into evacuated blood collection tube(s) or blood culture bottle(s) for in vitro diagnostic testing.	The Luer access device- holder with preattached multiple sample adapter is a sterile, non-invasive device used to connect devices with male or female Luer connectors to blood collection tubes for the collection of blood.

The proposed and predicate device have the same basic indication for use, the collection of a blood sample using a male or female Luer connector on a multiple sample adapter with a preattached holder. All devices use an ISO 594 connector of various gender (male/female) connected to a compatible 6% Luer to transfer blood into an evacuated container (blood collection tube, blood culture bottle) for in vitro diagnostic testing. The differences in the indications statement are in language and do not pose new questions of safety or effectiveness.

Substantial Equivalence

The subject and predicate device are substantially equivalent as described in Table 3.

Table 2: Substantial Equivalence Comparison

Characteristic	**Subject Device** **BD Vacutainer® Luer-Lok™ Access Device, BD Vacutainer® Blood Transfer Device**	**Predicate Device** **Luer Access Device-holder with preattached multiple sample adapter** **K200027**	**Comparison**
Product Code	JKA	JKA	Same
Regulation Number	21 CFR 862.1675	21 CFR 862.1675	Same
Class	II	II	Same
Number of Uses	Single Use	Single Use	Same
Material	Hub (Polycarbonate) Non-patient (NP) Cannula (Stainless Steel) Rubber Sleeve (Isoprene Rubber) Holder (Polypropylene (PP)) Bonding agent/adhesive*	Luer Lock Male Hub (MABS) Non-patient Needle/Tube (Stainless Steel) Rubber Sleeve (Isoprene Rubber) Holder (PP)	Difference in Hub Material. The use of a different polymer for the hub component does not raise new questions of safety or effectiveness of the device.
Label/Labeling	Conform with 21 Part 801	Conform with 21 Part 801	Same
Length	BTD: 61.98 mm (2.44 in), LLAD: 63.42 mm (2.50 in)	60.8±0.2mm	Difference in Length. This difference does not affect the intended use or performance of the device or raise new questions of safety or effectiveness.
ISO 594	Compliant	Compliant	Same
Biocompatibility	ISO 10993 Compliant including: • In vitro toxicity • Skin sensitization • Intracutaneous Reactivity • Acute System Toxicity • Hemocompatibility	ISO 10993 Compliant including: • In vitro toxicity • Skin sensitization • Intracutaneous Reactivity • Acute System Toxicity • Hemocompatibility	Same
Sterilization Method	EO	EO	Same
Sterilization Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Connector Type	Luer-Lok™ Access Device – Male Luer Blood Transfer Device – Female Luer	Male & Female Luers	Same

Characteristic	**Subject Device** **BD Vacutainer® Luer-Lok™ Access Device and BD Vacutainer® Blood Transfer Device**	**Predicate Device** **Luer Access Device-holder with preattached multiple sample adapter** **K200027**	**Comparison**
Sample Collected	Blood	Blood	Same

The clearance for the predicate K200027 did not list the bonding agent used.

Difference in Hub Material: The materials of hub from proposed device are different with predicate device. However, the biocompatibility test for proposed device has been tested and the results comply with the requirements of ISO 10993. Therefore, this difference is not determined to affect substantial equivalence or safety/effectiveness.

Difference in Length: The length of between the proposed device and predicate device is different. This difference in length is not substantial. This difference does not affect intended use or the performance of the device. Therefore, this difference does not affect substantial equivalence or safety/effectiveness.

Difference in precautions: The proposed Luer-Lok™ Access Device has an added precaution for use in urinalysis to address reported adverse events associated with reasonably foreseeable misuse. This difference does not affect substantial equivalence or safety/effectiveness. This difference does not affect the Blood Transfer Device.

Conclusion: The differences between proposed device and predicated device include materials of manufacture, product length and device labeling. These differences do not raise any question regarding its safety and effectiveness. The differences in technological characteristics may be evaluated through performance testing.

Non-clinical Performance Testing:

1. **Performance Testing**

   ISO 594-1-1986 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements

   ISO 594-2-1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment —Part 2: Lock fittings

   EN ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods

   EN ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied

   EN ISO 14971:2012 Medical Devices – Application of risk management to medical devices

2. **Sterilization, Package Integrity, Shipping and Shelf Life**

EN ISO 11135:2014 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization Residuals

EN ISO 11737-1:2019 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products

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

ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials

ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

3. **Biocompatibility**

BD Vacutainer® Luer-Lok™ Access Device and BD Vacutainer® Blood Transfer Device are classified as a surface medical devices that comes in contact with intact skin for a limited (≤24 hours) duration.

ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN ISO 10993-2:2006 Biological evaluation of medical devices - Part 2: Animal welfare requirements

ISO 10993-4:2017 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood

ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

ISO 10993-7:2008/AC:2009 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO 10993-23:2021, Biological Evaluation of Medical Devices - Part 23: Tests for irritation.

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.

- Torque to Break
- Torque to Unseat
- NP Cannula Pull Test
- Air Leakage Test
- Torque to Break
- Torque to Unseat
- NP Sleeve Function
- Package Integrity test
- Peel Strength Test
- Luer Compatibility as per ISO 594/80369-7.

Clinical Data

Not applicable

Conclusion

Based on the comparison and analysis above and the performance testing conducted, each of the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.