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Becton, Dickinson & Company  
Chelsea Woods, RAC  
Staff Regulatory Affairs Specialist  
1 Becton Drive  
Franklin Lakes, NJ 07417

Re: BK210649

Trade/Device Name: BD Vacutainer® ACD A Blood Collection Tube,  
BD Vacutainer® ACD B Blood Collection Tube

Regulation Number: 21 CFR 862.1675

Regulation Name: Blood specimen collection device

Regulatory Class: Class II

Product Code: JKA

Dated: October 22, 2021

Received: October 25, 2021

Dear Ms. Woods:

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 and Part 809); 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/combo-products/guidance-regulatory-information/postmarketing-safety-reporting-combo-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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh, MD  
Director  
Division of Blood Components and Devices  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research

Enclosure: Indications for Use

**Indications for Use**

**510(k) Number:** BK 210649

**Device Name:** BD Vacutainer® ACD A Blood Collection Tube, BD Vacutainer® ACD B Blood Collection Tube

**Indications for Use:**

BD Vacutainer® ACD A and B Blood Collection Tubes are evacuated, sterile, single use, in vitro diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment, preservation, and transport of human venous blood specimens for the purpose of in vitro diagnostic testing.

BD Vacutainer® ACD A and B Blood Collection Tubes may be used for testing in immunohematology, such as ABO grouping and Rh typing.

The performance characteristics of these tubes have not been established for immunohematology testing in general; therefore, users must validate the use of these tubes for their specific assay- instrument/reagent system combinations and specimen storage conditions.

Prescription Use \_\_\_\_\_ AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CBER, Office of Blood Research and Review (OBRR)

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Division Sign-Off, Office of Blood Research and Review