5 510(K) SUMMARY

5.1 Device Name

BD Vacutainer® ACD A and B Blood Collection Tubes

5.2 Summary Preparation Date:

10/22/2021

5.3 Submitted by:

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5.6 Proprietary Names:

BD Vacutainer® ACD A and B Blood Collection Tubes

5.7 Common or Usual Names:

Tubes, Vials, Systems, Serum Separators, Blood Collection

5.8 Regulatory Information

Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
Classification Regulation: 21 CFR §862.1675

Regulatory Class: Class II
Product Code: JKA

5.9 Predicate Device(s)

BD Vacutainer® ACD Blood Collection Tubes (Pre-Amendment)

5.10 Device Establishment

Becton, Dickinson and Company

5.11 Registration Number:

2243072

5.12 Performance Standards:

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

ANSI/AAMI/ISO 11137-1:2006, A1: 2013, A2 2018 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ANSI/AAMI/ISO 11137-2: 2013 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

ANSI/AAMI/ISO 11137-3:2017 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control

ANSI/AAMI/ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microrganisms on products

ANSI/AAMI/ISO 11737-2:2019 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

ANSI AAMI ST67:2019
Sterilization of health care products - Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile"

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

5.13 Intended 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.

5.14 Device Description

The BD ACD Tubes are evacuated glass blood collection tubes that are provided sterile.

The Acid Citric Dextrose (ACD) solution is comprised of Trisodium Citrate, Citric Acid and Dextrose, and are available with either ACD Solution A or ACD Solution B. ACD Solution A (ACD-A) consists of Trisodium Citrate, 22.0 g/L, Citric Acid, 8.0 g/L, and Dextrose, 24.5 g/L. ACD Solution B (ACD-B) consists of Trisodium Citrate, 13.2 g/L, Citric Acid, 4.8 g/L, and Dextrose, 14.7 g/L. Both ACD Solution A and B provide an anticoagulated specimen when used in accordance with the instructions for use.

The BD ACD tubes are closed with a conventional rubber stopper. All stopper/closures are color coded to reflect additive type (Yellow for BD ACD Tubes). The available draw volumes are 8.5mL for Solution A (16x100mm size) and 6mL for Solution B (13x100mm size).

5.15 Substantial Equivalence

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

Table 1: Substantial Equivalence Comparison

Characteristic	BD Vacutainer® ACD Blood Collection Tubes	BD Vacutainer® ACD Blood Collection Tubes Pre-Amendment	Comparison
Indications for Use	BD Vacutainer® ACD 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 Blood Collection Tubes are 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.	BD Vacutainer® ACD Blood Collection Tubes are intended for the collection of a plasma specimen in a closed evacuated system. The tube may be used for *in vitro* diagnostic testing where red cell preservation is required.	The preamendment BD ACD Tubes refer to "red cell preservation." The subject 510(k) submission for BD ACD Tubes includes more specific information, including use for testing in immunohematology. Immunohematology is the study of red blood cell antigens and antibodies. The proposed indications for use represents a subset of the prior indications for use and includes additional more detailed information consistent with current best practices; the changes do not result in a new intended use.
Intended Population	General Use – all populations	General Use – all populations	Identical
Evacuated Blood Collection Tube	Yes	Yes	Identical
Draw Volume	ACD-B: 6 mL ACD-A: 8.5 mL	ACD-B: 6 mL ACD-A: 8.5 mL	Identical
Sample Type	Plasma	Plasma	Identical
Additive Type	Acid Citric Dextrose	Acid Citric Dextrose	Identical

Characteristic	BD Vacutainer® ACD Blood Collection Tubes	BD Vacutainer® ACD Blood Collection Tubes Pre-Amendment	Comparison
Additive Quantity	Solution A: 22.0 g/L Trisodium Citrate 8.0 g/L Citric Acid 24.5 g/L Dextrose Solution B: 13.2 g/L Trisodium Citrate 4.8 g/L Citric Acid 14.7 g/L Dextrose	Solution A Solution B	Identical
Tube Dimensions	ACD-B: 13x100mm ACD-A: 16x100mm	ACD-B: 13x100mm ACD-A: 16x100mm	Identical
Tube Material	Glass	Glass	Identical
Tube Closure	Conventional yellow stopper	Conventional yellow stopper	Identical
Additive Dispense	Liquid Fill	Liquid Fill	Identical
Sterilization Method	Irradiation	Irradiation	Identical
Sterility Assurance Level (SAL)	10^{-3}	10^{-3}	Identical
Shelf Life	14 months	24 months	Shelf-life durations are based on test data currently available and additional testing is ongoing to support future shelf-life extensions. This difference does not raise new questions of safety or effectiveness.
Unit Labeling	Paper Label	Paper Label	Identical
Packaging	Unit – tube and closure Shelf – shrink wrapped polystyrene tray Case – corrugated cardboard	Unit – tube and closure Shelf – shrink wrapped polystyrene tray Case – corrugated cardboard	Identical

5.15.1 Discussion on Substantial Equivalence

Intended Use

The preamendment BD ACD Tubes refer to “red cell preservation.” The subject 510(k) submission for BD ACD Tubes includes more specific information, including use for testing in immunohematology. Immunohematology is the study of red blood cell antigens and antibodies. The proposed indications for use represent a subset of the prior indications for use and includes additional more detailed information consistent with current best practices; the changes do not result in a new intended use.

The intended use of the subject BD ACD tubes is a subset of the prior indications for use of the pre-amendment BD ACD tubes that were displayed, advertised, or otherwise offered for sale before May 28, 1976, as a device intended for the collection, processing, and transportation of a plasma specimen in a closed evacuated system. Like the predicate device, the tube is used in settings where a venous blood sample is collected by a trained healthcare worker.

Therefore, both the subject and predicate device have the same intended use and substantially similar indications for use, meeting the first criteria for a finding of substantial equivalence.

Technological Characteristics

Both the subject and pre-amendment BD ACD tubes have similar technological characteristics. Like the pre-amendment BD ACD tubes, the subject device consists of Acid Citric Dextrose (ACD), provided as either Solution A or Solution B. The tubes continue to be made of glass, come in two different sizes and draw volumes. Further, the closure type and color of the tubes are substantially the same (conventional yellow stoppers).

Changes to the tube shelf-life and some materials/processing methods have been implemented since May 28, 1976. However, these differences do not raise new questions of safety or effectiveness. Furthermore, performance testing demonstrates that the modifications do not impact the safety or effectiveness of the device and that the subject BD ACD Tubes continue to perform as intended.

Principles of Operation

Both the subject and pre-amendment tubes are used for plasma preparation and are made of glass for the collection of venous blood which upon centrifugation separates plasma for use in immunohematology. The anticoagulant-additive mixture in ACD tubes contains trisodium citrate, citric acid, and dextrose. The dextrose in this solution is a nutrient to enable the cells to metabolize and be viable. The principles of operation are unchanged compared to the predicate device.

5.16 Performance Testing – Non-Clinical Summary

Non-clinical performance testing was conducted following defined protocols and with established acceptance criteria to evaluate the following attributes of the BD ACD tubes at time-zero and over the proposed shelf life: Draw Volume, X-Value, Second Stopper Pullout, Stopper Leakage, Tube Leakage, and Resistance to Breakage During Centrifugation. Additionally, Ship Testing was conducted to assess the functional performance of the packaging materials. The BD ACD tubes met all non-clinical testing requirements at time-zero and over the product shelf life.

The BD ACD Tubes met all non-clinical testing requirements at time-zero and over the product shelf life, demonstrating that the device functions as designed. These performance tests demonstrate that the modifications to the device do not impact its safety or effectiveness and that the subject BD ACD Tubes continue to perform as intended.

5.17 Performance Testing – Animal Summary

No animal studies were performed in support of this submission.

5.18 Performance Testing – Clinical Summary

Clinical testing was conducted on blood collected in both the subject device (BD Vacutainer® Glass Whole Blood ACD Blood Collection Tubes), and a legally marketed comparator device to demonstrate Clinical Equivalence. Additional clinical testing was completed to evaluate Within-Tube Stability, Shelf-Life Performance, and Repeatability/Reproducibility. Clinical testing was conducted for a representative panel of immunohematology test parameters, with the distribution of ABO grouping/Rh typing subjects selected to be approximately representative of the general US population.

Results based on pre-determined acceptance criteria demonstrated the BD ACD tubes are suitable for use in immunohematology testing.

5.19 Conclusion

The technical performance characteristics of the subject device are unchanged. The proposed BD Vacutainer® ACD Blood Collection Tubes and predicate device of the same name have the same intended use, principle of operation, and technological characteristics. Non-Clinical and Clinical Performance Testing sufficiently support the determination that the changes made to the BD Vacutainer® ACD Blood Collection Tubes do not raise any new concerns of safety or effectiveness. Based on information provided in this submission the proposed device is substantially equivalent to the predicate device.