June 21, 2023

PreAnalytiX GmbH
c/o Alexandra Kirby
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, NJ 07417

Re: K231469
Trade/Device Name: PAXgene® Blood DNA Tube
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: PJE
Dated: May 22, 2023
Received: May 22, 2023

Dear Alexandra Kirby:

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/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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Division Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K231469

Device Name
PAXgene® Blood DNA Tube

Indications for Use *(Describe)*
The PAXgene® Blood DNA Tube is intended to collect, anticoagulate, stabilize, transport, and store a venous whole blood sample for preparation of human DNA for use with molecular diagnostic test methods that require DNA. The performance characteristics of this device have not been established for molecular diagnostic assays in general. Users must validate use of product for their specific molecular diagnostic assay.

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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510(K) SUMMARY

PAXgene® Blood DNA Tube

510(k) Submission Number: K231469

Summary Preparation Date: June 20, 2023

Submitted by:
PreAnalytiX GmbH
Garstligweg 8
Hombrechtikon, CH 8634

Contact:
Alexandra Kirby
Staff Regulatory Affairs Specialist
1 Becton Drive, Franklin Lakes, NJ 07417
Email: Alexandra.Kirby@bd.com
Phone: (862) 774-2318

Proprietary Names: PAXgene® Blood DNA Tube

Catalog Number: 761165

Common or Usual Names: Blood Collection Device

Regulatory Information
Classification Name: Blood Specimen Collection Device
Classification Regulation: 21 CFR 862.1675
Regulatory Class: Class II
Product Code: PJE Blood/Plasma Collection Device for DNA Testing
Classification Panel: Clinical Chemistry

Predicate Device: K142821, PAXgene® Blood DNA Tube

Establishment Registration Information

Manufacturing/Sterilization Site:	Becton, Dickinson and Company Belliver Industrial Estates, Belliver Way, Roborough Plymouth, PL6 &BP UK FDA Facility Registration Number: 9617032
Parent Company:	PreAnalytiX GmbH Garstligweg 8 Hombrechtikon, CH 8634 FDA Facility Registration Number: 3005202328

Performance Standards:

1. EN ISO 13485:2016/A11:2021 Medical devices – Quality management systems – Requirements for regulatory purposes

2. EN ISO 14971:2019/A11:2021 Medical Devices – Application of risk management to medical devices

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

4. EN ISO 11137-1:2015/A2:2019 Sterilization of health care products - Radiation Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

5. EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

6. EN ISO 11737-1:2018/A1:2021 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products

7. EN 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

8. EN 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

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

10. EN ISO 18113-1:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements

11. EN ISO 18113-3:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: *In vitro* diagnostic instruments for professional use

12. EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer

13. EN 62366-1:2015/AC:2016-09 Medical Devices Part 1: Application of usability engineering to medical devices

14. EN 13612:2002 Performance evaluation of *in vitro* diagnostic medical devices

15. EN ISO 14001:2015 Environmental management systems - Requirements with guidance for use

16. ISO 6710:2017 Single-use containers for venous blood specimen collection

17. EN 17141:2020 Cleanrooms and associated controlled environments. Biocontamination control

18. EN ISO 14644-1:2015 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particles concentration

19. EN ISO 14644-2:2015 Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

20. ASTM D5276:2019 Standard Test Method for Drop Test of Loaded Containers by Free Fall

21. ASTM D4169:2016 Standard Practice for Performance Testing of Shipping Containers and Systems

22. ASTM D4728:2017 Standard Test Method for Random Vibration Testing of Shipping Containers

23. ASTM D999:2008 (R2015) Standard Test Methods for Vibration Testing of Shipping Containers

Indications for Use

The subject and predicate PAXgene® Blood DNA Tube share the same indications for use:

> The PAXgene® Blood DNA Tube is intended to collect, anticoagulate, stabilize, transport, and store a venous whole blood sample for preparation of human DNA for use with molecular diagnostic test methods that require DNA. The performance characteristics of this device have not been established for molecular diagnostic assays in general. Users must validate use of product for their specific molecular diagnostic assay.

As both the subject and predicate devices have the same indications for use, this does not raise any new questions of safety or effectiveness.

Device Description

The subject PAXgene® Blood DNA Tube has the same device description, key design features, principles of operation, intended use, indications for use, product labeling, packaging, sterilization, shelf life, and performance characteristics as the predicate PAXgene® Blood DNA Tube cleared

under K142821. The subject change of this special 510(k), a revised draw volume specification, does not alter these characteristics.

The PAXgene® Blood DNA Tube is a sterile, single use, plastic, evacuated blood collection tube with a BD Hemogard™ closure assembly (comprised of Hemogard™ stopper and shield components) and a measured quantity of K_2EDTA additive. The additive quantity dispensed into each tube is designed to match the nominal blood draw volume of 2.5 mL. The tube is made of polyethylene terephthalate (PET) plastic which functions to maintain vacuum within the tube, allowing for accurate and consistent blood draw for the duration of the shelf life of the tube. A predetermined vacuum is drawn inside the tube that is sealed with a BD Hemogard™ closure which consists of a rubber stopper plus BD Hemogard™ shield.

The PAXgene® Blood DNA Tube is available as a 13 x 75 mm tube with a 2.5 mL nominal blood draw. The referenced first dimension represents the diameter of the tube, and the second dimension represents the length of the tube.

Substantial Equivalence

The subject and predicate device are substantially equivalent as described in Table 9.

Table 9: PAXgene® Blood DNA Tube Substantial Equivalence Comparison

Characteristic	Subject Device PAXgene® Blood DNA Tube	Predicate Device PAXgene® Blood DNA Tube K142821	Comparison
General Description	The PAXgene® Blood DNA Tube is a sterile, single use, plastic, evacuated blood collection tube with a BD Hemogard™ closure assembly and a measured quantity of K_2EDTA additive. The additive quantity dispensed into each tube is designed to match the nominal blood draw volume of 2.5 mL. The tube is made of polyethylene terephthalate (PET) plastic which functions to maintain vacuum within the tube, allowing for accurate and consistent blood draw for the duration of the shelf life of the tube. A predetermined vacuum is drawn inside the tube that is sealed with a BD Hemogard™ closure which consists of a rubber stopper plus BD Hemogard™ shield.	The PAXgene® Blood DNA Tube is a sterile, single use, plastic, evacuated blood collection tube with a BD Hemogard™ closure assembly and a measured quantity of K_2EDTA additive. The additive quantity dispensed into each tube is designed to match the nominal blood draw volume of 2.5 mL. The tube is made of polyethylene terephthalate (PET) plastic which functions to maintain vacuum within the tube, allowing for accurate and consistent blood draw for the duration of the shelf life of the tube. A predetermined vacuum is drawn inside the tube that is sealed with a BD Hemogard™ closure which consists of a rubber stopper plus BD Hemogard™ shield.	Identical
Indications for Use	The PAXgene® Blood DNA Tube is intended to collect, anticoagulate, stabilize, transport, and store a venous whole blood sample for preparation of human DNA for use with molecular diagnostic test methods that require DNA. The performance characteristics of this device have not been established for molecular diagnostic assays in general. Users must validate use of product for their specific molecular diagnostic assay.	The PAXgene® Blood DNA Tube is intended to collect, anticoagulate, stabilize, transport, and store a venous whole blood sample for preparation of human DNA for use with molecular diagnostic test methods that require DNA. The performance characteristics of this device have not been established for molecular diagnostic assays in general. Users must validate use of product for their specific molecular diagnostic assay.	Identical
Device Design			
Design/Function	Evacuated blood collection tube	Evacuated blood collection tube	Identical
Dimensions	13 mm x 75 mm	13 mm x 75 mm	Identical
Nominal Draw Volume	2.5 mL	2.5 mL	Identical
Closure	BD Hemogard™ closure consisting of a rubber stopper plus BD Hemogard™ shield	BD Hemogard™ closure consisting of a rubber stopper plus BD Hemogard™ shield	Identical

Characteristic	Subject Device PAXgene® Blood DNA Tube	Predicate Device PAXgene® Blood DNA Tube K142821	Comparison
Draw Volume Specification	+10% to −25% of the labelled draw volume	+10% to −19% of the labelled draw volume	The difference in draw volume specification extends the lower specification limit for blood draw volume of the PAXgene® Blood DNA Tube. The revised draw volume specification for the subject device, +10% to −25%, is supported by clinical evidence and there are no new questions of safety and effectiveness.
Device Materials			
Tube Material	Polyethylene terephthalate (PET)	Polyethylene terephthalate (PET)	Identical
Tube Stopper Lubricant	Silicone	Silicone	Identical
Anticoagulant	K_2EDTA	K_2EDTA	Identical
Injection molding (tube/Hemogard™ closure	Injection molded	Injection molded	Identical
Rubber molding (stopper)	Compression molded rubber	Compression molded rubber	Identical
Interior Coating	Spray coated/Dried	Spray coated/Dried	Identical
Evacuation	Vacuum chamber	Vacuum chamber	Identical
Packaging and Sterility			
Tube Sterility	Sterile	Sterile	Identical
Sterilization Method	Gamma irradiation	Gamma irradiation	Identical
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Identical
Shelf Life	12 months	12 months	Identical
Shelf-Case/Pack Level	Shrink-wrapped expanded polystyrene (EPS) tray	Shrink-wrapped expanded polystyrene (EPS) tray	Identical
Shipper/Case Level	Corrugated cardboard	Corrugated cardboard	Identical

As provided in Table 9, the subject PAXgene® Blood DNA Tube and the predicate PAXgene® Blood DNA Tube cleared under K142821 use the same operating principles, incorporate the same detailed designs, are manufactured from the same materials, are sterilized using the same method (gamma irradiation) with the same SAL of 10^{-6}, use the same technological characteristics, have identical shelf lives (12 months), are packaged using the same shelf-case/pack and shipper/case materials, and have the same indications for use.

The difference of the draw volume specification between the subject and predicate PAXgene® Blood DNA Tubes has been supported by clinical evidence and shelf-life testing, which do not raise different questions of safety and effectiveness.

Performance Testing – Bench Summary

Device testing was conducted to validate that the device performs as intended over the course of the product shelf life. Results of testing demonstrate acceptable performance.

Performance Testing – Animal Summary

No animal testing was conducted to support the change in draw volume specification for the subject devices.

Performance Testing – Clinical Summary

Clinical testing was conducted to validate that the device performs as intended. Results of the testing demonstrate acceptable performance.

Conclusion

In summary, the subject PAXgene® Blood DNA Tube is as safe and effective as the predicate PAXgene® Blood DNA Tube cleared under K142821. The subject PAXgene® Blood DNA Tube has the same indications for use, technological characteristics, and principles of operation as the predicate PAXgene® Blood DNA Tube cleared under K142821. The differences in draw volume specification between the subject and predicate PAXgene® Blood DNA Tubes do not raise new issues of safety or effectiveness. Bench and clinical testing demonstrate acceptable performance.

Based on information provided, the subject PAXgene® Blood DNA Tube is substantially equivalent to the predicate PAXgene® Blood DNA Tube cleared under K142821.