July 19, 2024

Greiner Bio-One North America Inc
Manfred Abel
Regulatory Affairs & Quality Systems Manager
4238 Capital Drive
Monroe, North Carolina 28110

Re: K233979
Trade/Device Name: VACUETTE® QUICKSHIELD Complete (Plus)
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA, FMI
Dated: June 20, 2024
Received: June 20, 2024

Dear Manfred Abel:

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.

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

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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233979

Device Name
VACUETTE® QUICKSHIELD Complete (Plus)

Indications for Use *(Describe)*
The VACUETTE® QUICKSHIELD Complete is intended to be used only with VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. They are for single-use only and should be used by properly trained healthcare professionals only in accordance with these instructions.

The VACUETTE® QUICKSHIELD Complete PLUS is intended to be used only with VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. VACUETTE® VISIO PLUS Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognize successful vein penetration. They are for single- use only and should only be used by adequately trained healthcare personnel in accordance with these instructions.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K233979 - PREMARKET NOTIFICATION 510(K) SUMMARY

1. SUBMITTER

Applicant name:
Greiner Bio-One GmbH.
Bad Haller Strasse 32
4550 Kremsmünster,
Austria

Contact person:
Manfred Abel
Greiner Bio-One NA Inc.
4238 Capital Drive
Monroe, NC 28110
Phone +1 704 261 7800
manfred.abel@gbo.com

Establishment registration number: 8020040

Date prepared: July 19, 2024

2. DEVICE

Trade name: VACUETTE® QUICKSHIELD Complete (Plus)

Common name: Safety tube holder pre-assembled with the needle

Regulation: 862.1675, Blood Specimen Collection Device

Primary classification product code: JKA – Blood specimen collection device

Subsequent classification product code: FMI – Needle, hypodermic, single lumen

Medical device class: II

Review panel: General Hospital

3. PREDICATE DEVICES

Primary predicate device:
Blood Collection Needle with/without Holder,
Safety Blood Collection Needle with/without Holder,
Luer Access Device-holder with Pre-attached Multiple Sample Adapter (K200027)

Secondary predicate device: VACUETTE® QUICKSHIELD Complete (K072320)

4. DEVICE DESCRIPTION

The sterile VACUETTE® QUICKSHIELD Complete is a single packed VACUETTE® QUICKSHIELD Safety Tube Holder with pre-threaded VACUETTE® Multiple Use Drawing Needle in a blister pack. It is a sterile, single-use plastic tube holder, designed with a safety shield, which can be activated to cover the needle immediately following venipuncture.

The sterile VACUETTE® QUICKSHIELD Complete PLUS is a single packed VACUETTE® QUICKSHIELD Safety Tube Holder with pre-threaded VACUETTE® VISIO PLUS Blood Collection Needle in a blister pack. It is a sterile, single-use plastic tube holder, designed with a safety shield, which can be activated to cover the

needle immediately following venipuncture.

5. INDICATION FOR USE

The VACUETTE® QUICKSHIELD Complete is intended to be used only with VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. They are for single-use only and should be used by properly trained healthcare professionals only in accordance with these instructions.

The VACUETTE® QUICKSHIELD Complete PLUS is intended to be used only with VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. VACUETTE® VISIO PLUS Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognize successful vein penetration. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with these instructions.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Greiner Bio-One NA Inc. believes that the VACUETTE® QUICKSHIELD Complete (Plus) is substantially equivalent in intended use, indications for use, principles of operation, and technological characteristics to the predicate devices. Any differences between VACUETTE® QUICKSHIELD Complete (Plus) and the predicate devices do not raise new types of safety or effectiveness issues, as further discussed below.

	Candidate Device	**Primary Predicate Device**	**Secondary Predicate Device**	**Remark**
Name	VACUETTE® QUICKSHIELD Complete (Plus)	Blood Collection Needle with/without Holder, Safety Blood Collection Needle with/without Holder, Luer Access Device-	VACUETTE® QUICKSHIELD Complete	n/a
510(k) Number	K233979	K200027	K072320	n/a
Classification	Class II	Class II	Class II	n/a
Regulation	862.1675	862.1675	880.5570	n/a
Product Code	Primary product code: JKA	Primary product code: JKA	FMI	n/a
	Subsequent product code: FMI	Subsequent product code: FMI		

Indications for Use	The VACUETTE® QUICKSHIELD Complete is intended to be used only with VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. They are for single-use only and should be used by properly trained healthcare professionals only in accordance with these instructions. The VACUETTE® QUICKSHIELD Complete PLUS is intended to be used only with VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury VACUETTE® VISIO PLUS Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognize successful vein penetration. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with these instructions.	The Blood Collection Needle with/without holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The Safety Blood Collection Needle with/without holder is intended to be used with vacuum blood collection. tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury. 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 QUICKSHIELD Complete is intended to be used only with VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions. This device is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. VACUETTE® VISIO PLUS Blood Collection Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognize successful vein penetration. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with these instructions.	Different. S&E evaluated by external and internal performance testing, see further information below.

Manufacturer	Greiner Bio-One (GBO)	Jiangsu Caina Medical Co., Ltd	Greiner Bio-One (GBO)	n/a
Safety mechanism	Active safety mechanism. One-hand activation.	The safety shield is intended to prevent needle sticks. Only on the Safety	Active safety mechanism. One-hand activation.	Same
	Manual operation for activation.	Manual	Manual operation for activation.	
Cannula variants	• Multiple Sampling Needle (K973620) • Visio Plus Needle (K061483)	Various gages and length	• Multiple Samling Needle (K973620) • Visio Plus Needle (K061483)	SE
Cannula Gauges	21G or 22G	27G, 25G, 23G, 22G, 21G, 20G, 18G	21G or 22G	SE
Cannula Length	1” or 1.25” or 1.5”	1” or 1.25” or 1.5”	1” or 1.25” or 1.5”	SE
Sterile	Yes	Yes	Yes	SE
SAL	10^{-6}	10^{-6}	10^{-6}	SE
Sterilization	E-Beam Irradiation	ETO	ETO	Different, evaluation according to ISO 11137-1 and ISO 11137-2.
Non-pyrogenic	Yes	Yes	Yes	SE
Materials – comply with ISO 10993-1	Yes	Yes	Yes	SE
Use	Single use only	Single use only	Single use only	SE
Materials:				
Needle Cap	PP	Same	Same	SE
Needle	Stainless Steel AISI 304	same	Same	SE
Rubber sleeve	Rubber Sleeve	Rubber Sleeve	Rubber Sleeve	SE
Holder	PP	Same	Same	SE
Safety shield	PP	Same	Same	SE
Connection of:				
Needle and Holder	Pre-attached	Pre-attached	Pre-attached	SE
Holder and shield	Rotational shield	n/a	Non-rotational shield	Different, S&E evaluated by internal test method

Comparison of Technological Characteristics

As can be seen in the above table a comparison of the design of the VACUETTE® QUICKSHIELD Complete (Plus) and its features show that both the candidate device and the predicate devices have the same fundamental scientific technology and technological characteristics. The VACUETTE® QUICKSHIELD Complete (Plus) and the predicate devices include the same safety mechanism covering the needle after the blood collection. The used safety mechanisms need to be activated manually. After manual activation of the safety mechanism of candidate device as well as the predicate devices the safe and locked position of the safety

mechanism is reached by the Quickshield-needle-cover. The used materials for all products are the same or at least comparable and the differences do not have an influence on the safety and effectiveness of the candidate device. The candidate device and the predicate devices are provided sterile and single use only.

Comparison of Intended Use
The above comparison table shows the indications for use of the candidate device as well as predicate devices. The indications are comparable in their content so that all products are intended to be used for venous blood collection.

7. PERFORMANCE DATA

The VACUETTE® QUICKSHIELD Complete (Plus) is manufactured and verified by testing in conformity with applicable recognized consensus standards like ISO 23908, ISO 7864, and ISO 9626 but not limited to those standards. Simulated use tests were performed for venous blood collection procedure as well as the functionality of the safety mechanism was tested.

The VACUETTE® QUICKSHIELD Complete (Plus) is manufactured and tested in conformity with internal specifications and recognized consensus standards. Performance testing was conducted to demonstrate and support our substantial equivalency claim that the device performs as intended and in an equivalent manner as the predicate devices.

Requirement	Outcome (Pass or fail)
Force to remove shield	**Pass**
Torque to rotate shield	**Pass**
Torque to screw out needle	**Pass**
Spin out	**Pass**
Force to activate safety mechanism	**Pass**
Force necessary to bend safety shield with needle by 90°	**Pass**
Puncture force	**Pass**
Friction force	**Pass**
Leakage	**Pass**

Sterility testing:
VACUETTE® QUICKSHIELD Complete (Plus) are sterilized by e-beam irradiation for a final Sterility Assurance Level (SAL) of 10^{-6} per ISO 11137-1 Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices. Bioburden testing for determination of verification dose and subsequently the processing dose was performed in accordance with ISO 11737-1 – Sterilization of medical devices – microbiological methods – Part 1: Determination of a population of microorganisms on products.

Biocompatibility testing:
Biocompatibility for the VACUETTE® QUICKSHIELD Complete (Plus) was performed in accordance with the standards of the ISO 10993 series and under consideration of the *Guidance for industry and Food and Drug Administration Stuff – Use of the International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (Attachment A: Table A.1 Endpoints to be addressed in a biological risk assessment). The holder was classified as "surface device with short term contact to intact skin", and the cannula was classified as "external communicating device with short term contact to the blood path." Based on the classification the following biological endpoints were evaluated, and it was demonstrated that the candidate device meets the following standards:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-23)
- Hemocompatibility (ISO 10993-4)
- Material mediated pyrogenicity (ISO 10993-11)
- Acute Systemic Toxicity (ISO 10993-11)

8. CONCLUSION

The test results and the comparison table above show the VACUETTE® QUICKSHIELD Complete (Plus) is substantially equivalent to its predicate devices with respect to intended use, technological and performance characteristics and does not raise new safety or effectiveness concerns.