April 19, 2018

Greiner Bio-One NA Inc
Manfred Abel
Quality Systems and Regulatory Affairs
4238 Capital Drive
Monroe, North Carolina 28110

Re: K173757
Trade/Device Name: VACUETTE EVOPROTECT Safety Blood Collection / Infusion Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 12, 2018
Received: March 13, 2018

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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K. Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173757

Device Name
VACUETTE EVOPROTECT Safety Blood Collection/Infusion Set

Indications for Use *(Describe)*
The VACUETTE EVOPROTECT Safety Blood Collection/Infusion Set is indicated for venous blood collection and/or the short-term infusion of intravenous fluids. It is to be used by appropriately trained healthcare professionals in accordance with the 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.

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SECTION 5. PREMARKET NOTIFICATION 510(K) SUMMARY: K173757

1. SUBMITTER

Applicant Name: Greiner Bio-One GmbH.
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Austria

Contact person: Manfred Abel, M.S., MBA
Greiner Bio-One NA Inc.
4238 Capital Drive
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Manfred.Abel@gbo.com

Establishment registration number: 8020040

Date prepared: Apr. 17, 2018

2. DEVICE

Trade Name: VACUETTE® EVOPROTECT Safety Blood Collection/Infusion Set

Common name: Blood Collection Set

Classification:

Name:	Needle, hypodermic, single lumen
Product Code:	FMI
Regulation No:	880.5570
Class:	2
Review Panel:	General Hospital

3. PREDICATE DEVICE

Predicate: VACUETTE SAFETY BLOOD COLLECTION SET & SAFETY INFUSION SET (K121908)

4. DEVICE DESCRIPTION

The VACUETTE® EVOPROTECT SAFETY Blood Collection/Infusion Set is a single-use, sterile, winged needle bonded to flexible tubing with a Luer connector and a semi-automatic release of the safety mechanism. The winged needle is designed with a safety mechanism, which allows for activation ensuring the needle is covered immediately following venipuncture to aid in the protection against accidental needlestick injury. The EVOPROTECT Safety Blood Collection/Infusion Set is individually wrapped, sterile with a luer port. The luer port can be used to connect FDA cleared accessories like luer adapter, holder, etc.

5. INDICATION FOR USE

The VACUETTE EVOPROTECT Safety Blood Collection/Infusion Set is indicated for venous blood collection and/or the short-term infusion of intravenous fluids. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject device and the predicate device have the same fundamental technology, technological characteristics, and intended use.

Based on the device features, principles of operation and technological characteristics, the VACUETTE® EVOPROTECT Safety Blood Collection/Infusion Set is substantially equivalent to the predicate device.

	NEW GBO Product VACUETTE® EVOPRTOTECT Safety Blood Collect/ Infusion set	**Predicate Device VACUETTE® Safety Blood Collection / Infusion set**	**Comparison**
FDA Status	Under review	K121908	NA
Classification	Class II	Class II	same
Regulation	880.5570	880.5570	same
Classification Product Code	FMI	FMI	same
Intended Use	The VACUETTE EVOPROTECT Safety Blood Collection/Infusion Set is indicated for venous blood collection and/or the short-term infusion of intravenous fluids. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.	The SAFETY Blood Collection/Infusion Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a luer connector. The Vacuette Safety Blood Collection/Infusion Set is used for blood collection and/or the short-term infusion of intravenous fluids. The winged needle 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.	same
Sterile	yes	yes	same

	NEW GBO Product VACUETTE® EVOPRTOTECT Safety Blood Collect/ Infusion set	**Predicate Device VACUETTE® Safety Blood Collection / Infusion set**	**Comparison**
Device Characteristics			
Safety mechanism	Semi-passive safety mechanism. One-hand activation.	Active safety mechanism. One-hand activation.	equivalent
	Manual operation for activation (i.e. release). Afterwards spring force driven motion in safe position.	Manual operation for activation (i.e. release). Afterwards manual driven motion in safe position.	equivalent
Cannula Gauges	21/23/25	21/23/25	same
Cannula Length	¾"	¾"	same
Sterile	Yes	Yes	same
Storage	4 – 25 C°	4 – 36 C°	equivalent
Use	Single use only	Single use only	same
Tubing Lengths	4"; 7½"; 12"	4"; 7½"; 12"	same
Materials: All data as detailed and as known:			
Needle Cap	PP	PP	same
Needle	Stainless Steel AISI 304	Stainless Steel AISI 304	same
Wing	TPE	PVC	equivalent
Protector	PC	PC	same
Hub	PMMA	PMMA	same
Activation spring / manual	Stainless Steel Spring AISI 301	manual	equivalent
Stopper	ABS	ABS	same
Tubing	PVC with plasticizer	PVC with plasticizer	same
Connector	ABS	ABS	same
Connector Cap	PP	PP	same
Adhesive	UV cured adhesive	Solvent bonding	equivalent
Packaging	Blister	Pouch	equivalent

The above table shows that the VACUETTE® EVOPROTECT Safety Blood Collection/Infusion Set is equivalent to the predicate device. The differences in storage, wing material, activation, adhesive and packaging is equivalent as demonstrated in the performance testing.

7. PERFORMANCE DATA

The VACUETTE® EVOPROTECT Safety Blood Collection/Infusion Set is manufactured and tested in conformity with a variety of recognized consensus standards. Performance data show that the device performs as intended and in an equivalent manner as the predicate devices.

Requirement	Acceptance	Results pass/fail
Penetration resistance Cap	Penetration resistance >3N for 21G, 23G and 25G. Equivalent to predicate device.	pass
Cannula cleanliness	Tested in accordance with to ISO 7864:2014	pass
Cannula radial orientation	Equivalent to predicate device.	pass
Cannula puncture & friction force 21G	Equivalent to predicate device	pass
Cannula puncture & friction force 23G	Equivalent to predicate device	pass
Cannula puncture & friction force 25G	Equivalent to predicate device	pass
Cannula bond force 21G	Tested in accordance with ISO 7864:2016	pass
Cannula bond force 23G	Tested in accordance with ISO 7864:2016	pass
Cannula bond force 25G	Tested in accordance with ISO 7864:2016	pass
Flow rate water 10cm tubing, 21G (extreme: max flow rate over all variants)	Equivalence, internal Specification	pass
Flow rate water 19 cm tubing, 21G	Equivalence, internal Specification	pass
Flow rate water 19 cm tubing, 23G	Equivalence, internal Specification	pass
Flow rate water 30 cm tubing, 23G	Equivalence, internal Specification	pass
Flow rate water 30cm tubing, 25G (extreme: min flow rate over all variants)	Equivalence, internal Specification	pass
Breaking compressive force cannula before activation	Tested in accordance with ISO 23908:2011	pass
Size designation	Tested in accordance with ISO 9626:2016	pass
Dimensional	Tested in accordance with ISO 9626:2016	pass
Resistance for stiffness	Tested in accordance with ISO 9626:2016	pass
Resistance for breakage	Tested in accordance with ISO 9626:2016	pass
Resistance for corrosion	Tested in accordance with ISO 9626:2016	pass

Requirement	Acceptance	Results pass/fail
Activation force safety mechanism	Tested in accordance with ISO 23908:2016	pass
Breaking force safety mechanism compression	Tested in accordance with ISO 23908:2011	pass
Breaking force safety mechanism tension	Tested in accordance with ISO 23908:2011	pass
Bond strength Hub to Stopper	Equivalence, ISO 8536-4:2010 + Amd 1:2013	pass
Bond strength Tubing to Stopper	Equivalence, ISO 8536-4:2010 + Amd 1:2013	pass
Bond strength Tubing to Connector	Equivalence, ISO 8536-4:2010 + Amd 1:2013	pass
Tubing breaking force	Equivalence, ISO 8536-4:2010 + Amd 1:2013	pass
Detaching torque Luer Adapter (LA) to Connector	Equivalent to predicate device	pass
Detaching force Luer Adapter to Connector	Equivalent to predicate device	pass
Spring characteristic	Equivalent to ISO 23908:2011, simulated use	pass
Leakage of product (pressure & vacuum)	Equivalent to predicate device	pass
Simulated use	According to intended use and specification	pass
Tightness single packaging (Bubble test)	According to ASTM F2096-04	pass
Tightness single packaging (Dye penetration)	According to ASTM F1929-15, ISO 11607-2 and EN 868-5	pass
Sealing strength and max. opening force single packaging	According to ISO 11607-1 and EN 868-5	pass
Biocompatibility testing	Testing according to ISO 10993-1 and FDA guidance	pass
Sterility testing	Testing according to 11137-1	pass

Sterility testing

VACUETTE® EVOPROTECT Safety Blood Collection/ Infusion Sets are sterilized by irradiation for a final Sterility Assurance Level (SAL) of 10^{-6} in accordance with ISO 11137-1 Sterilization of health care products. Bacterial endotoxin testing was performed by according to ANSI/AAMI ST72:2011.

Biocompatibility testing

Biocompatibility for the VACUETTE® EVOPROTECT Safety Blood Collection/Infusion Set was performed in accordance with standards of the ISO 10993 series and others to demonstrate that the subject device meets requirements of the following standards:

- Cytotoxicity (ISO 10993-5, USP 38: 2016)
- Sensitization (ISO 10993-10:2010, ISO 10993-12 2012)
- Irritation (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11, USP 39 and ASTM F 750-87)
- Pyrogenicity (USP 39<151>)

- Hemocompatibility (ISO 10993-4, ASTM F756)
- Particulate Matter (USP 788)
- Genotoxicity characterization of extractable (ISO 10993-3)

8. CONCLUSION

Results from the performance verification and validation show that the EVOPROTECT Safety Blood Collection/Infusion Set meets established performance criteria and performance is as intended and substantially equivalent to the predicate device.