DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 3, 2016

Greiner Bio-One North America, Inc.
Manfred Abel
Quality System and Regulatory Affairs
4238 Capital Drive
Monroe, North Carolina 28110

Re: K160532
Trade/Device Name: Greiner Holdex® Single-Use Holder PP
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: October 28, 2016
Received: November 1, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang
-S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160532

Device Name

Greiner HOLDEX® Single-Use Holder PP

Indications for Use *(Describe)*

The HOLDEX® Single-Use Holder PP is for use in venous blood collection procedures in combination with blood collection devices with a female luer port.

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."

Premarket notification 510(k) Summary

1. SUBMITTER

Applicant Name:

Greiner Bio-One GmbH.
Bad Haller Strasse 32
4550 Kremsmuenster,
Austria

Contact person:

Manfred Abel, M.S., MBA
Greiner Bio-One NA Inc.
4238 Capital Drive
Monroe, NC 28110
704 261 7823
Manfred.Abel@gbo.com

Establishment registration number: 8020040

Date prepared: September 16, 2016

2. DEVICE

Trade Name: Greiner HOLDEX® Single-Use Holder PP

Common name: Greiner Holdex

Classification: Trade Name: Greiner HOLDEX® Single-Use Holder PP
Regulation Number: 880.5570
Regulation name: Needle, hypodermic, single lumen
Regulation Number: 880.5570
Regulatory Class: II
Product Code: FMI
General Hospital

3. PREDICATE DEVICES

Primary Predicate: Trade Name: Vacuette HOLDEX Single-Use Holder PP (K980768)
Regulation Number: 880.5570
Regulation name: Needle, hypodermic, single lumen
Regulatory Class: II
Product Code: FMI
General Hospital

Secondary Predicate: Trade Name: Becton Dickinson Brand Multiple Sample Luer Adapter (K991088)
Regulation Number: 862.1675
Regulation name: tubes, vials, systems, serum separators, blood collection
Regulatory Class: II
Product Code: JKA
Clinical Chemistry

4. DEVICE DESCRIPTION

The Greiner HOLDEX Single-Use Holder PP is a disposable plastic holder, which consists of a cylinder made from polypropylene plastic with an off-center molded male luer at the top. The off-center location of the male luer is to facilitate venipuncture when using luer needles. A stainless steel needle with a sleeve is bonded to the inside of the holder to facilitate blood draw by puncturing the cap of an attached blood collection device. The sleeve is made from Synthetic Polyisoprene Compound.

The purpose of this submission is to obtain premarket clearance in order to market the HOLDEX® Single-Use Holder PP for the extended indication for use.

5. INDICATION FOR USE

The HOLDEX® Single-Use Holder PP is for use in venous blood collection procedures in combination with blood collection devices with a female luer port.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

	Greiner Vacuette HOLDEX Single-use Holder PP	**Greiner Vacuette HOLDEX Single-use Holder PP (primary predicate)**	**BD Vacutainer Luer-Lok Access Device (secondary predicate)**
FDA status	Under review	K980768	K991088
Classification	Class II	Class II	Class II
Regulation	880.5570	880.5570	862.1675
Product Code	FMI	FMI	JKA
Intended Use	The HOLDEX Single-Use holder PP is for use in venous blood collection procedures in combination with blood collection devices with a female luer port.	To be used in routine venipuncture procedures using butterfly needles and/or hypodermic luer needles.	The VACUTAINER Brand Luer Adapter is a sterile, non-invasive device used to connect venous access devices such as needles, blood collection sets, and infusion sets to blood collection tubes. They are also used in connection with non-needle devices for collection of blood from catheters. The VACUTAINER Brand Luer Adapter is sold by itself and as a component of other VACUTAINER Brand devices.
Manufacturer	Greiner Bio-One (GBO)	Greiner Bio-One (GBO)	Becton, Dickinson and company (BD)
Sterilizer	Mediscan GmbH	Mediscan GmbH	Not known
Needle Insert	Polypropylene	Polypropylene	Plastic
Sleeve	Does not contain dry natural rubber	Contains natural rubber compound	Does not contain dry natural rubber
Needle	Stainless Steel	Stainless Steel	Not known
Sterilization	E-Beam	E-Beam	Gamma
Storage	4 – 25 C°	4 – 25 C°	4 – 25 C°
Use	Single use only	Single use only	Single use only

The indications for use of the Greiner HOLDEX under review are similar to the predicate devices. The subject device and the primary predicate device have been used for the intended use of the primary predicate device according to K980768. The subject device and the primary predicate device are also equivalent in design, performance and materials. The intended use of the subject device for venous blood collection procedures in combination with blood collection devices with a female luer port is considered substantially equivalent to the intended use of the secondary predicate device (K991088) to be used in connection with non-needle devices for collection of blood from catheters.

7. PERFORMANCE DATA

Performance testing was done to demonstrate that the Greiner HOLDEX can be used for venous blood collection procedures in combination with blood collection devices with a female luer port.
The Greiner HOLDEX is made and verified by testing in conformity to ISO 594-1 for the luer part. In addition, simulated venous blood draw testing was performed on the HOLDEX Single-Use Holder PP using 180 blood collection devices with female luer ports of common brands which are legally marketed on the US market while following the Instructions for Use for the Greiner HOLDEX:

- 383540 / BD: Nexiva™ Closed IV Catheter System; 18 GA 1.75 IN; 1.3 x 45mm; 4740 ml/hr 79 ml/ min
- 383662 / BD: Nexiva Q-Syte™ Luer Access Split-Septum; 22 GA 1.00 IN; 0.9 x 25mm; 1980 ml/hr, 33 ml/min
- 382933 / BD: Insyte Shielded I.V. Catheter; BD Insyte Autoguard BC Winged; 20 GA 1.00 IN; 1.1 x25mm; 63 ml/min
- 4253574-01 / Bbraun: Introcan Safety Winged – PUR; 20G x 1” (1.1 x 25mm); 65 ml/min
- 4253540-01 / Bbraun: Introcan Safety Winged – PUR; 22G x 1” (0.9 x 25mm); 35 ml/min
- 4057 / Jelco / Smiths Medical: Jelco® I.V. Catheter Radiopaque (20G, 1”, 25 mm, 1.15 mm, 65 ml/min)

8. DISCUSSION / CONCLUSION

We compared the performance of the Greiner HOLDEX to the similar indications of use of the predicate devices. The results showed that the Greiner HOLDEX performed without failure and leakage. Based on the device features, principles of operation, technological characteristics and indications for use of the current Greiner HOLDEX we conclude that the subject device performs in a substantially equivalent manner to the predicate devices.