DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 6, 2017

GREINER BIO-ONE NA INC.
MANFRED ABEL
QUALITY SYSTEM AND REGULATORY AFFAIRS
4238 CAPITAL DRIVE
MONROE NC 28110

Re: K163436
Trade/Device Name: Greiner Vacuette Urine Count and Culture, Mannitol Tube
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport culture medium
Regulatory Class: I
Product Code: JSM, LIO
Dated: December 5, 2016
Received: December 7, 2016

Dear Mr. 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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), 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,

Steven R. Gitterman -S

for Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
K163436

Device Name
Greiner Vacuette Urine Count and Culture, Mannitol tube

Indications for Use *(Describe)*
The Greiner Vacuette Urine Count and Culture, Mannitol tube is a urine stabilization device intended for collection, transport and storage of urine for bacterial and yeast culture. Urine samples collected in the Greiner Vacuette Urine Count and Culture, Mannitol tube can be stored at 20-25°C for up to 48 h prior to culture. This device is intended for professional use only.

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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SECTION 5. 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
704 763 0855
Manfred.Abel@gbo.com

Establishment registration number: 8020040

Date prepared: Nov 23, 2016

2. DEVICE - CLASSIFICATION

Trade Name:	Greiner Vacuette Urine Count and Culture, Mannitol tube
Common name:	Greiner Vacuette CCM tube
Device:	Culture Media, Non-Propagating Transport
Regulatory Description:	Transport culture medium
Regulation Medical Specialty:	Microbiology
Product Code:	JSM
Regulation No:	866.2390
Class:	1
Review Panel:	Microbiology

3. PREDICATE DEVICE - CLASSIFICATION

Device name:	BD Vacutainer Plus Plastic Urine C&S Tube
510(k) number:	K024240
Device:	Culture Media, Non-Propagating Transport
Regulatory Description:	Transport culture medium
Regulation Medical Specialty:	Microbiology
Product Code:	JSM
Regulation No:	866.2390
Class:	1
Review Panel:	Microbiology

4. DEVICE DESCRIPTION

Vacuette Urine CCM tubes are tubes made of PET with a pre-defined vacuum to exact draw volumes. They are fitted with yellow Vacuette Safety Caps. The tube interior is sterile.

The evacuated tube contains a fine particle granulate stabilizer to preserve the urine sample at 20-25°C for up to 48 hours. The stabilizer helps to preserve and protect the level of bacteria at collection and maintain typically formed elements in urine sediment.

5. INDICATION FOR USE

The Greiner Vacuette Urine Count and Culture, Mannitol tube is a urine stabilization device intended for collection, transport and storage of urine for bacterial and yeast culture. Urine samples collected in the Greiner Vacuette Urine Count and Culture, Mannitol tube can be stored at 20-25°C for up to 48 h prior to culture. This device is intended for professional use only.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject device and the predicate have the same fundamental scientific technology and technological characteristics. Both devices are comprised of clear plastic tubes.

	Greiner Vacuette Urine CCM tube (Count & Culture Mannitol)	**BD Vacutainer Plus Plastic Urine C&S Tube (Culture and Sensitivity)**
FDA status	Under review	K024240
Classification	Class 1	Class 1
Regulation	866.2390	866.2390
Product Code	JSM	JSM
Intended Use	The Vacuette Urine CCM tube is a urine stabilization device intended for collection, transport and storage of urine for bacterial and yeast culture. Urine samples collected in the Vacuette® Urine CCM tube can be stored at 20-25°C for up to 48 h prior to culture. This device is intended for professional use only.	The BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tubes and Kits are intended for the collection and transport of urine samples for culture and sensitivity testing of bacteria. The BD Vacutainer Plus Plastic Urine C&S Preservation Tube is filled with lyophilized urine maintenance formula and evacuated to draw approximately 4 – 10 ml (depending on the tube size) of urine. The lyophilized urine maintenance formula can maintain the bacterial population in the urine specimen for a period of 48 hours at room temperature levels comparable to those urine specimens without additive, held under refrigeration for the same period of time
Manufacturer	Greiner Bio-One (GBO)	Becton, Dickinson and company (BD)
Tube	clear plastic	clear plastic and glass
Tube volume	13x75 mm - 4ml 16x100 mm - 5ml 16x100 mm - 10ml	13x75 mm - 4ml 16x75 mm - 5ml 16x100 mm - 10ml
Cap	Safety cap, yellow	Conventional stopper, gray
Vacuum	predefined Vacuum	predefined Vacuum
Additive	boric acid, sodium formate, sodium borate, mannitol	boric acid, sodium formate, sodium borate

Storage	20 – 25 °C	normal room condition
Storage stability at room temperature	48 hours	48 hours
Sterile	Yes	yes

The intended use of the Greiner Vacuette Urine CCM tube is similar to the predicate device. Both devices are intended for the collection and storage of urine samples for culture at room temperature for up to 48 hours. Based on the device features, principles of operation, and technological characteristics we believe Greiner CCM tube is substantially equivalent to the predicate device.

7. PERFORMANCE DATA

Testing was performed for the suitability of Greiner CCM tube as sampling and transport system for microbiological specimen using procedures outlined in the Clinical Laboratory Standard Institute (CLSI) M40-A2 Quality Control of Microbiological Transport Systems. Viability and recovery testing was performed with recommendation from M40-A2 and FDA, ATCC cultures from 10 potential pathogens of Escherichia coli, Enterococcus faecalis, Proteus mirabilis, Pseudomonas aeruginosa, Staphylococcus saprophyticus, Enterobacter cloacae, Klebsiella pneumoniae, Streptococcus agalactiae, Candida albicans, Candida glabrata were used to spike sterile filtered urine to 10^2, 10^3 and 10^4 cfu/ml.
All analyses were performed in triplicates at room temperature and refrigerated temperature.

8. DISCUSSION / CONCLUSION

The *GBO CCM* tube fulfills the requirements set in the CLSI standard M40-A2, “Quality Control of Microbiological Transport Systems” demonstrating that the recovered organism are within +/- 1 log from the original spiked concentration is considered acceptable performance. The data provided shows that acceptable performance was demonstrated for all organisms tested.