510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K163436

B. Purpose for Submission:

To make a substantial equivalence determination for the Greiner Vacuette Urine Count and Culture, Mannitol tube for the collection, transport and storage of urine specimens for laboratory culture of bacteria and yeast.

C. Measurand:

Not Applicable

D. Type of Test:

Transport Culture Medium Device

E. Applicant:

Greiner Bio-One NA, Inc.

F. Proprietary and Established Names:

Greiner Vacuette Urine Count and Culture, Mannitol tube

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.2390; Transport Culture Medium

2. Classification:

   Class I

3. Product code:

   JSM; Culture Media, Non-Propagating Transport
   LIO: Device, Specimen Collection

4. Panel:

   83- Microbiology

H. Intended Use:

1. Intended use(s):

   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.

2. Indication(s) for use:

   Same as the Intended use

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   None.

I. Device Description:

The Greiner Vacuette Urine Count and Culture, Mannitol (CCM) tubes are tubes made of polyethylene terephthalate (PET) with a pre-defined vacuum to exact draw volumes. They are fitted with yellow Vacuette Safety Caps.

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

J. Substantial Equivalence Information:

1. Predicate device name(s):

   BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tubes and Kits

2. Predicate 510(k) number(s):

   k024240

3. Comparison with predicate:

Similarities		
Item	**Greiner Vacuette Urine CCM tube K163436**	**BD Vacutainer Plus Plastic Urine C&S Tube K024240**
Intended 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.	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.
Single use device	Yes	Same
Volume	predefined Vacuum	Same
Storage	20 – 25 °C	Same
Storage stability at room temperature	48 hours	Same
Sterile	Yes	Same

Differences		
Item	**Greiner Vacuette Urine CCM tube K163436**	**BD Vacutainer Plus Plastic Urine C&S Tube K024240**
Tube	clear plastic	clear plastic and glass
Additives	boric acid, sodium formate, sodium borate, mannitol	boric acid, sodium formate and sodium borate
Tube sizes	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

K. Standard/Guidance Document Referenced (if applicable):

Quality Control of Microbiological Transport Systems; Approved Standard, M40-A2, Clinical and Laboratory Standards Institute (CLSI), Wayne, PA. 2014.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The performance characteristics of the Greiner Vacuette Urine CCM tubes were determined using organism recovery (i.e., viability) studies. The bacteria listed in Table 1 below were evaluated in this study. The organisms evaluated were representatives from bacterial species that are usually associated with urinary tract infections. Inoculation and organism recovery studies conducted in accordance with the Clinical Laboratory Standards Institute (CLSI) M40-A2 document.

To perform viability studies, organisms were diluted from 1.5 x 10^8 CFU/mL (equivalent to a 0.5 McFarland standard) down then spiked into pooled filter sterilized urine to get a final concentration of 1.5 x 10^4, 1.5 x 10^3, and 1.5 x 10^2 CFU/mL. The spiked urine samples were then placed in their respective Greiner Vacuette Urine CCM tubes in triplicates and held for 0, 24, 48 hours at room temperature (20-25°C) and at refrigerated temperature (2-8°C). At the designated time intervals, the Greiner Vacuette Urine CCM tubes were removed from storage and 100µL from each urine tube was removed and plated. The average plate count results from the organism recovery study are shown in Table 1 below. Demonstrating that the recovered organism concentration is within +/- 1 log of the original spiked concentration is considered acceptable performance. The data provided shows that acceptable performance was demonstrated for all organisms tested.

Table 1. Organism recovery results

Organism	Hold Temperature	Average CFU/mL Recovered: Time 0 hrs	Average CFU/mL Recovered: Time 48 hrs	T=48 hrs Log reduction (-) Log increase (+)
Escherichia coli **(ATCC 25922)**	2-8°C	7.0×10^3	4.0×10^3	-0.39
	20-25°C	6.9×10^3	3.7×10^3	-0.27
Enterococcus faecalis **(ATCC 29212)**	2-8°C	6.9×10^3	6.5×10^3	-0.03
	20-25°C	6.0×10^2	2.8×10^3	0.56
Proteus mirabilis **(ATCC 7002)**	2-8°C	2.0×10^3	1.5×10^3	-0.11
	20-25°C	2.0×10^3	1.4×10^3	-0.14
Pseudomonas aeruginosa **(ATCC BAA-427)**	2-8°C	6.3×10^3	4.8×10^3	-0.11
	20-25°C*	6.5×10^2	2.4×10^2	-0.44
Staphylococcus saprophyticus **(ATCC 15305)**	2-8°C	6.1×10^3	2.6×10^3	-0.38
	20-25°C	6.2×10^3	3.7×10^3	-0.23
Enterobacter cloacae **(ATCC 13047)**	2-8°C	1.0×10^3	3.4×10^2	-0.49
	20-25°C	1.3×10^4	2.4×10^3	-0.73
Klebsiella pneumonia **(ATCC 13883)**	2-8°C	6.4×10^3	5.2×10^3	-0.09
	20-25°C	7.0×10^3	5.9×10^3	-0.08
Streptococcus agalactiae **(ATCC 13813)**	2-8°C	7.9×10^3	4.4×10^3	-0.25
	20-25°C	7.1×10^3	4.9×10^3	-0.16
Candida albicans **(ATCC 24433)**	2-8°C	1.9×10^3	7.4×10^2	-0.43
	20-25°C	1.8×10^3	3.0×10^2	-0.78
Candida glabrata **(ATCC 2001)**	2-8°C	3.5×10^3	1.6×10^3	-0.34
	20-25°C	4.2×10^4	1.6×10^4	-0.44
0.5 McFarland microorganism suspension was diluted and spiked into clinically negative urine. 100µL of spiked urine was plated on each plate for the 0hrs time point. *200µL of spiked urine was plated on each plate for the 0hr time point.				

a. *Precision/Reproducibility:*

Not Applicable

b. *Linearity/assay reportable range:*

Not Applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Shelf life: The shelf life for the Greiner Vacuette Urine CCM tube is 14 months after the date of manufacture. The stability of the vacuum tubes was performed on a total of five lots of Greiner Vacuette Urine CCM tubes. Tube vacuum stability was done in real time. At time point zero, four tubes from each lot were averaged together to ensure that they met (or did not exceed by more than 10%) the predetermined fill volume (10 mL, 5 mL or 4 mL). The rest of the lot was kept at room temperature and periodically tested at one, three, six, nine, 12, 14,and 20 months. At each time point 25 tubes per lot were tested for vacuum fill volume. Tubes were demonstrated to have enough vacuum to autofill within 10% of the deigned fill volume for each of the three sizes and for all the time points out to 14 months.

Sterilization: The Greiner Vacuette Urine CCM tubes are sold as sterile by e-beam irradiation. Irradiation was set at 16.6 KG. Bioburden testing was conducted on expired vials. The 14 month sterility claim was supported based on data demonstrating no growth detected up to this period.

d. *Detection limit:*

Not Applicable

e. *Analytical specificity:*

Not Applicable

f. *Assay cut-off:*

Not Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Method comparison is not applicable for a bacterial transport medium. The device itself does not provide a result that can be used in making a clinical decision. Bench testing studies were done to determine the ability of the Greiner Vacuette Urine CCM tube to maintain viability of microorganisms commonly found as the etiological agents of urinary tract infections. The microorganisms were spiked into filter sterilized pooled urine for testing. The Greiner Vacuette Urine CCM tube showed recovery of representative bacteria from pooled urine within the acceptance criteria recommended in CLSI-M40-A2. (See section M.1. above).

b. *Matrix comparison:*

Not Applicable

3. Clinical studies:

   a. Clinical Sensitivity:

   Not Applicable

   b. Clinical specificity:

   Not Applicable

   c. Other clinical supportive data (when a. and b. are not applicable):

   Not Applicable

4. Clinical cut-off:

   Not Applicable

5. Expected values/Reference range:

   Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.