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

A. 510(k) Number:

K180052

B. Purpose for Submission:

To make a substantial equivalence determination for the the UriSwab - Urine Collection, Transport and Preservation System for the collection, transport and storage of urine specimens for laboratory culture of uropathogenic bacteria and yeast.

C. Measurand:

Not Applicable

D. Type of Test:

Transport Culture Medium Device

E. Applicant:

Copan Italia S.p.A.

F. Proprietary and Established Names:

UriSwab - Urine Collection, Transport and Preservation System

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):

   Copan UriSwab - Urine Collection, Transport and Preservation System is intended for the collection, transport and preservation of urine specimens from the collection site to the testing laboratory. In the laboratory, UriSwab specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.

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:

Copan's UriSwab is a ready-to-use Urine Collection, Transport and Preservation System consists of a screw cap self-standing tube with a conical shaped bottom. Inside the tube, the cap holds a plastic stick with sponges made of hydrophilic polyurethane. The sponges incorporate preservative substances. The UriSwab device sustains the viability of organisms during transport for up to 48 hours at 2-25 °C. Two types of collection systems are available; the regular size (100 mm length X 16 mm diameter) plastic tube and the mini size (80 mm length x 12 mm diameter) plastic tube.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   BD Vacutainer Plus Plastic Urine C&C Tube and Kits

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

   K024240

3. Comparison with predicate:

Similarities		
Item	**Copan UriSwab – Urine Collection, Transport and Preservation System (K180052)**	**Predicate: BD Vacutainer Plus Plastic Urine C&S Tube & Kits (K024240)**
Product Code	JSM, LIO	JSM
Intended Use	Copan UriSwab – Urine Collection, Transport and Preservation System is intended for the collection, transport and preservatrion of urine specimens from the collection site to the testing laboratory. In the laboratory, UriSwab specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.	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.
Single use device	Yes	Same
Device Storage Temperature	2-25ºC	4-25ºC
Urine Specimen Stability at Room Temperature	Up to 48 hours	Same
Sterile	Yes	Same
Tube	Plastic	Same

Differences		
Item	**Copan UriSwab – Urine Collection, Transport and Preservation System (K180052)**	**Predicate: BD Vacutainer Plus Plastic Urine C&S Tube & Kits (K024240)**
Inoculated Device Temperature	2-25 ºC	20-25 ºC
Additives	Boric acid, sodium formate	Boric acid, sodium formate and sodium borate
Collection device	Plastic tube, stick with sponge	Plastic holder plus needle
Fill volume	Depending on the Uriswab product and packaging, the absorbed urine volume from sponges will be approximately 1.5 mL or 3.2 mL with a corresponding released volume post-centrifugation of 1.0 mL and 2.9 mL, respectively	4-10 mL urine
Sample Handling (Urine Release Method)	Two procedures can be performed to release the absorbed urine on the sponge (Centrifugation or Manual release)	Not applicable

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., 2015.

Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, 1st edition, 11137-1, International Organization for Standarization (ISO), 2006.

Sterlization of health care products - Radiation - Part 2: Establishing the sterilization dose, 3rd edition, 11137-2, International Organization for Standarization (ISO), 2013.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Microorganism recovery (viability) study:
The performance characteristics of UriSwab were determined using organism recovery (i.e., viability) studies. The bacteria and fungi listed in **Table 1** below were evaluated in this study. The organisms evaluated are representatives from bacterial species that are usually associated with urinary tract infections. Inoculation and organism recovery studies were conducted based on the general principles outlined in the Clinical Laboratory Standards Institute (CLSI) M40-A2 document.

To perform viability studies, organisms were diluted from 1.5×10^8 colony forming units per milliliter (CFU/mL) (equivalent to a 0.5 McFarland standard) down into filtered synthetic urine to a final concentration of 1.5×10^4, 1.5×10^3, and 1.5×10^2 CFU/mL. UriSwab was inoculated by submerging the sponge applicator for 5 seconds in each dilution. For each organism, 45 devices were inoculated and microorganism viability was determined by quantitative culture to determine viable count (CFU/mL). At time zero, 9 devices were centrifuged immediately after inoculating UriSwab. All remaining devices were either held at refrigerated temperature (2-8ºC) or room temperature (20-25ºC) and organism viability was assessed at 24 and 48-hr post-storge. For each holding temperature and time point evaluated, urine was eluted from 9 devices by centrifugation and plated in triplicate to determine the CFU/mL. Plate counts represent the average of three plates. Results are shown in **Table 1** below and demonstrate less than 1 $\log_{10}$ increase or reduction for all organisms tested. This is acceptable.

Table 1. Performance of UriSwab in maintaining the viability of urinary tract microorganisms

Recovery of Urine Culture Organisms in UriSwab					
Organism	Hold Temperature	Average CFU/mL Recovered: Time 0 hrs	Average CFU/mL Recovered: Time 24 hrs	Average CFU/mL Recovered: Time 48 hrs	T = 48 hours Log reduction (-) or increase (+)
C. albicans (ATCC 24433)	2-6ºC	7.37×10^2	4.70×10^2	3.92×10^2	-0.27
	20-24ºC	7.37×10^2	3.79×10^2	3.11×10^2	-0.37
E. coli (ATCC 25922)	2-6ºC	2.15×10^3	1.78×10^3	1.16×10^3	-0.28
	20-24ºC	2.15×10^3	1.22×10^3	4.26×10^2	-0.71
E. faecalis (ATCC 29212)	2-6ºC	2.11×10^3	1.64×10^3	1.72×10^3	-0.09
	20-24ºC	2.11×10^3	1.18×10^3	1.04×10^3	-0.31
P. aeruginosa (ATCC 27853)	2-6ºC	2.40×10^3	1.96×10^3	1.70×10^3	-0.15
	20-24ºC	2.40×10^3	1.34×10^3	5.31×10^2	-0.66
P. mirabilis (ATCC 7002)	2-6ºC	4.33×10^2	3.76×10^2	3.23×10^2	-0.13
	20-24ºC	4.33×10^2	2.96×10^2	1.47×10^2	-0.47
S. saprophyticus (ATCC 15305)	2-6ºC	9.67×10^2	6.11×10^2	5.02×10^2	-0.28
	20-24ºC	9.67×10^2	5.54×10^2	5.11×10^2	-0.28
Recovery of Additional Relevant Pathogenic Organisms of the Urinary Tract in UriSwab					
Organism	Hold Temperature	Average CFU/mL Recovered: Time 0 hrs	Average CFU/mL Recovered: Time 24 hrs	Average CFU/mL Recovered: Time 48 hrs	T = 48 hours Log reduction (-) or increase (+)
C. freundii (ATCC 8090)	2-6ºC	2.36×10^3	2.06×10^3	1.76×10^3	-0.13
	20-24ºC	2.36×10^3	1.75×10^3	1.55×10^3	-0.19
C. glabrata (ATCC MYA-2950)	2-6ºC	1.52×10^3	7.78×10^2	6.21×10^2	-0.39
	20-24ºC	1.52×10^3	5.38×10^2	3.23×10^2	-0.67
E. cloacae (ATCC 13047)	2-6ºC	1.01×10^3	8.53×10^2	6.83×10^2	-0.29
	20-24ºC	1.01×10^3	6.71×10^2	1.40×10^3	0.15
M. morganii (ATCC 25829)	2-6ºC	2.27×10^3	2.19×10^3	1.38×10^3	-0.22
	20-24ºC	2.27×10^3	1.61×10^3	1.40×10^3	-0.21
S. agalactiae (ATCC 12386)	2-6ºC	2.26×10^3	1.85×10^3	1.23×10^3	-0.29
	20-24ºC	2.26×10^3	1.15×10^3	8.39×10^2	-0.45

Microorganism release study (Centrifugation and Manual release methods):
A limited study was performed to evaluate the ability of the UriSwab sponge to successfully release absorbed microorganisms by centrifugation and manual release methods. The organisms listed in **Table 2** below were evaluated in this study. These studies were performed as described in "**Microorganism recovery (viability) study**", with the following modifications: Within two minutes of UriSwab inoculation, urine was eluted either by centrifugation at 104Xg for 3 seconds or manual extraction, which entails shaking the device down three times using quick, sharp, downward wrist motions. Eluent was removed and spread in triplicate on the appropriate agar. A time-zero control (representing spiked urine) was also plated in triplicate. Microorganism release was evaluated by calculating the $\log_{10}$ value of microorganism concentration in the UriSwab eluent obtained by centrifiguation and manual release methods versus the zero-time control. Results are shown in **Table 2** and demonstrate no difference in organism release

(based on CFU/mL) between the two release methods.

Table 2. Performance of UriSwab in releasing uropathogenic microorganisms using the centrifuge and manual release methods

Organism	Average CFU/mL Recovered: Spiked Urine	Average CFU/mL Recovered: Time = 0 Centrifugation Release	Average CFU/mL Recovered: Time = 0 Manual Release	Centrifugation Release vs. Spiked Urine Log reduction (-) or increase (+)	Manual Release vs. Spiked Urine Log reduction (-) or increase (+)
C. albicans (ATCC 24433)	6.17×10^2	5.38×10^2	5.47×10^2	-0.06	-0.05
E. coli (ATCC 25922)	1.39×10^3	1.49×10^3	1.46×10^3	0.03	0.02
S. saprophyticus (ATCC 15305)	1.19×10^3	$1.19 \times 10^{3*}$	1.22×10^3	-0.002	0.01

* CFU/mL for this sample was 1.186×10^3 before rounding to two decimal places.

Fill volume study: A fill volume study was performed to demonstrate that underfilling of UriSwab does not negatively affect viability of urine flora. In order to test the worst-case-scenario, UriSwab Shelf-life results were analyzed and the three organisms with the highest log reduction were chosen for this study and are listed in **Table 3**. Microorganisms were diluted from 1.5×10^8 CFU/mL (equivalent to a 0.5 McFarland standard) down into filtered synthetic urine to a final concentration of 1.5×10^5, 1.5×10^4, and 1.5×10^3 CFU/mL. A smaller volume (10 uL) of eluent was plated to allow plate counts to fall in the countable range. UriSwab was inoculated by submerging the sponge applicator for 5 seconds in tubes that contained 300 uL of each dilution. For each organism, 18 devices were inoculated and organism recovery was evaluated for nine devices at time zero and nine devices 48 hours post-storage at 20-24ºC. Microorganisms were eluted by centrifugation and 10 uL of elute was plated in triplicate for each inoculated device. Plate counts represent an average of three plates. The log reduction of these organisms was less than 1 $\log_{10}$ at 48 hours. These results are acceptable.

Table 3. Results of UriSwab fill volume study

Organism	UriSwab Lot	Average CFU/mL Recovered: Time 0 hrs	Average CFU/mL Recovered: Time 48 hrs	T = 48 hours Log reduction (-) or increase (+)
E. coli (ATCC 25922)	D5L400	1.73×10^4	2.67×10^3	-0.81
	E4KH00	1.90×10^4	3.63×10^3	-0.72
	F4IS00	2.17×10^4	2.35×10^3	-0.97
P. aeruginosa (ATCC 27853)	D5L400	1.22×10^4	1.69×10^3	-0.86
	E4KH00	9.70×10^3	1.35×10^3	-0.86
	F4IS00	1.02×10^4	1.33×10^3	-0.89
P. mirabilis (ATCC 7002)	D5L400	1.96×10^4	2.97×10^3	-0.82
	E4KH00	2.13×10^4	2.48×10^3	-0.93
	F4IS00	1.50×10^4	2.80×10^3	-0.73

a. Precision/Reproducibility:

Not Applicable

b. Linearity/assay reportable range:

Not Applicable

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

Shelf life: UriSwab shelf life is up to 24 months after the date of manufacture for use to collect and store urine samples at 2-25ºC. To substantiate this claim, shelf life stability testing was performed on three lots of UriSwab mini-size tubes stored at temperatures of 4±2ºC or 30±2ºC for up to 24 months. For each lot, tests were conducted at T=1, 12, and 24 months after date of production. The organisms included in this study can be found in **Table1**, section "Recovery of Urine Culture Organisms in UriSwab". For each organism and each post-production time point, 45 devices were inoculated and microorganism viability was determined by quantitative culture to determine colony forming units per mL. As a time-zero control, 9 devices were centrifuged immediately after inoculating UriSwab. All remaining devices were either held at refrigerated temperature (2-8ºC) or room temperature (20-25ºC) and organism viability was assessed at 24 and 48-hr post-storge. For each holding temperature and time point, urine was eluted from 9 devices by centrifugation and plated in triplicate to determine the CFU/mL. Plate counts represent the average of three plates. Results (not shown) demonstrate less than 1 $\log_{10}$ increase or reduction for all organisms tested. This is acceptable.

Sterlization: UriSwab tubes are sterilized using Gamma irradiation, with the dosage set at 25 kGy. Sterilization is validated following ISO 11137-1:2006, and ISO 11137-2 (2013), Sterilization of Health Care Products Radiation guidelines.

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 UriSwab - Urine Collection, Transport and Preservation System to maintain viability of microorganisms commonly found as the etiological agents of urinary tract infections. The analytical studies showed recovery of representative bacteria from filtered synthetic urine that are 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.