



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

I Background Information:

A 510(k) Number

K232565

B Applicant

Copan Italia S.p.A.

C Proprietary and Established Names

UriSponge

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JSM	Class I, reserved	21 CFR 866.2390 - Transport Culture Medium	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain substantial equivalence determination for the Copan UriSponge for urine collection, transport and preservation of urine specimens and processing by using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.

B Measurand:

Not applicable

C Type of Test:

Non-propagating urine transport device containing stabilizing reagents.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

None

IV Device/System Characteristics:**A Device Description:**

Copan's UriSponge - Urine Collection, Transport, and Preservation System consists of screw cap self-standing plastic tube with conical shaped bottom. Inside the tube, the cap holds a plastic stick with sponges made of hydrophilic polyurethane. The sponges include preservative substances (Sodium Propionate, and Potassium Sorbate). Two sizes of product are available: the regular tube size (100 mm length x 16 mm diameter) plastic tube, and the mini tube size (80 mm length x 12 mm diameter) plastic tube.

B Principle of Operation:

The UriSponge applicator stick has two (mini size) or three (regular size) cylindrical shaped sponges which are contained within appropriately sized sterile plastic tube with screw cap. The sponges contain the chemical preservatives (Sodium Propionate, and Potassium Sorbate). These chemical preservatives maintain the microbial load of bacteria and yeast in absorbed urine sample during the transport until they are received and tested in the laboratory by standard culture techniques.

V Substantial Equivalence Information:**A Predicate Device Name(s):**

UriSwab-Urine Collection, Transport and Preservation System

B Predicate 510(k) Number(s):

K180052

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>Device: K232565</u>	<u>Predicate: K180052</u>
Device Trade Name	UriSponge	UriSwab
General Device Characteristic Similarities		
Intended Use/Indications For Use	Copan UriSponge - Urine Collection,	Copan UriSwab - Urine Collection, Transport

	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, UriSponge specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.	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.
Single Use device	Yes	Same
Device storage temperature (prior to use)	2-25°C	Same
Specimen storage temperature after collection	2-25°C	Same
Urine Specimen Stability at Room Temperature	Up to 48 hours	Same
Sterile	Yes	Same
General Device Characteristic Differences		
Preservative ingredients	Sodium Propionate, and Potassium Sorbate	Boric Acid, and Sodium Formate

VI Standards/Guidance Documents Referenced:

1. ISO 11137-1:2006 (including Amendment 1:2013 and Amendment 2:2018), Sterilization of Health Care Products- Radiation-Part1: Requirements for development, validation, and routine control of a sterilization process for medical devices.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Not applicable

2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

Not applicable

4. Assay Reportable Range:

Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Shelf Life: A real-time shelf-life stability testing was conducted. Testing was conducted with 3 different lots of the mini version of the devices (80 mm length x 12 mm diameter) at each timepoint (at within 1 month after manufacture, at approximately 5-6 months after manufacture, at approximately 12 months after manufacture and at 13 months after manufacture). Physical, mechanical stability as well as sponge absorption and release volumes were evaluated using 30 devices from each lot. To determine the physical and the mechanical stability, each lot was inspected for device's appearance and integrity through the intended use workflow. Sponge absorption and release volume were also tested to determine physical stability. Preservative content of UriSponge was tested at each timepoint by high performance liquid chromatography (HPLC) method. All results met the study acceptance criteria to support a shelf-life stability of 12 months when stored at 2-25°C in appropriate storage environment.

Sterilization: UriSponge tubes are sterilized using irradiation, with the dosage set following ISO 11137-1:2006 (including Amendment 1:2013 and Amendment 2:2019), Sterilization of Health Care Products- Radiation-Part1: Requirements for development, validation, and routine control of a sterilization process for medical devices. The acceptable sterility assurance level (SAL) for the sterilized UriSponge product was determined to be 10^{-6} or greater.

6. Detection Limit:

Performance Testing - Recovery Studies:

A culture-based recovery study was performed to support that ability of the UriSponge device to keep microbial load stable in the collected urine up to 48 hours at both 2-8 °C and 19-25 °C. Recovery of *Escherichia coli* (ATCC 25922), *Streptococcus agalactiae* (ATCC 13813), *Enterococcus Faecalis* (ATCC 29212), *Pseudomonas aeruginosa* (ATCC 27853), *Proteus mirabilis* (ATCC 7002), *Staphylococcus saprophyticus* (ATCC 15305), *Enterobacter Clocae* (ATCC 13047), *Klebsiella pneumoniae* (ATCC 13883) and *Candida albicans* (ATCC 24433) were tested as representative strains for urine specimen. Pooled human negative clinical urine samples were used as the best representative of the intended use sample type for transport and downstream analysis. In brief, the samples were prepared by suspending each of above-indicated freshly cultured organisms into human negative clinical urine. A minimum of three different dilutions of stock culture were used to obtain a colony count of 25-250 per plate and the appropriate dilution factor was considered in determining the viable count in CFU/mL. Sponge applicator of UriSponge devices of three lots (new, middle aged, and recently expired) were immersed into contrived urine sample for 5 seconds and returned to UriSponge tube and incubated for 0 hrs. (less than 20-minutes), 24 hrs., and 48 hrs. at 2-8 °C and 19-25°C. At the end of each incubation period, the devices were centrifuged, and the

absorbed sample were released, and aliquots of sample were spread onto appropriate agar plates and incubated in appropriate environment for 24-48 hours. Following incubation, colony forming units (CFU) were counted. A colony count of 25-250 per plate for at least one dilution and the $\Delta\text{Log}_{10} \leq 1$ and ≥ -1 between the average CFU/plate values at time zero (T = 0 hrs.) and at specific specimen incubation time (e.g., 24 hrs., 48 hrs., etc.) were considered acceptable to support a specimen stability claim for each target organism.

Table 2 below summarize the microbial recovery performance of the UriSponge device when the specimen containing devices were stored at 2-8 °C and 19-25 °C.

Table 2: Microbial recovery results summary of Urisponge device.

Organism	Organism concentration at T = 0 hrs. (CFU/mL)	Incubation Temperature	Logarithmic difference in microbial recovery from the baseline (T= 0 hrs.) (-ve indicates reduction)	
			T = 24 hrs.	T = 48 hrs.
<i>C. albicans</i> (ATCC 24433)	5x10 ²	2-8°C	-0.02	-0.03
		19-25°C	0.18	0.38
<i>E. coli</i> (ATCC 25922)	1.5x10 ³	2-8°C	-0.11	-0.20
		19-25°C	-0.11	-0.14
<i>E. faecalis</i> (ATCC 29212)	7.5x10 ²	2-8°C	-0.19	-0.25
		19-25°C	-0.04	-0.07
<i>P. aeruginosa</i> (ATCC 27853)	1.5x10 ³	2-8°C	-0.10	-0.16
		19-25°C	-0.20	-0.30
<i>P. mirabilis</i> (ATCC 7002)	7.5x10 ²	2-8°C	-0.08	-0.05
		19-25°C	-0.10	-0.06
<i>S. saprophyticus</i> (ATCC 15305)	1.5x10 ³	2-8°C	-0.17	-0.21
		19-25°C	-0.16	-0.07
<i>E. cloacae</i> (ATCC 13047)	1.5x10 ³	2-8°C	-0.23	-0.26
		19-25°C	-0.27	-0.29
<i>K. pneumoniae</i> (ATCC 13883)	1.5x10 ³	2-8°C	-0.11	-0.06
		19-25°C	-0.21	-0.13
<i>S. agalactiae</i> (ATCC 13813)	1.5x10 ³	2-8°C	-0.35	-0.45
		19-25°C	-0.39	-0.53

Microbial recovery study results support the ability of UriSponge device to maintain the recovery of the tested microorganisms in urine samples up to 48 hours when stored at 2-8 °C or at 19-25°C.

Fill Volume Flex Study: Impact of undersaturation of UriSponge Device:

The applicator sponge in the Urisponge device contains preservative to stabilize the urine sample. In situations when the applicator sponge is not fully saturated with the absorbed urine due to sponge undersaturation, the concentrated preservative may result in the creation

of a toxic environment to the intended use organisms present in the urine sample. To determine the impact of sponge undersaturation on microbial recovery, a fill volume flex study was conducted with 3 newly manufactured lots and with three strains (*E. coli* ATCC 25922, *P. aeruginosa* ATCC 27853 and *S. agalactiae* ATCC 13813) that exhibited the highest log reduction at 72 hours incubation. First, a preliminary fill volume study was conducted by immersing the applicator sponge in urine sample at different depths and for different durations of time. Based on the minimum acceptable release volume ($\geq 200 \mu\text{l}$), the worst-case scenario for undersaturation was determined. Finally, a comparative microbial recovery evaluation (as described above) was conducted between the intended use workflow and the worst-case scenario. For both scenarios, a colony count of 25-250 per plate for at least one dilution and the $\Delta\text{Log}_{10} \leq 1$ and ≥ -1 between the average CFU/plate values between time zero ($T = 0$ hrs.) and at the end of final incubation time, were considered acceptable to support specimen stability. The study results for both the intended use workflow and the worst-case scenario met the study acceptance criteria. The results from the fill volume flex study thus indicate that there is no significant risk of toxicity to the intended use organism in the urine sample due to undersaturation of UriSponge device.

7. Assay Cut-Off:

Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable

2. Matrix Comparison:

Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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