October 11, 2024

Copan Italia S.p.A.
Silvia Caprini
Senior Regulatory Affairs Manager
via Francesco Perotti 10
Brescia, IT 25125
Italy

Re: K232565
Trade/Device Name: UriSponge
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: September 6, 2024
Received: September 6, 2024

Dear Silvia Caprini:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D., D(ABMM)
Branch Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232565/S002

Device Name
UriSponge™

Indications for Use *(Describe)*
Copan UriSponge™ - 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, UriSponge™ specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.

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.

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510(k) SUMMARY

1. General Information

Submitter name	COPAN ITALIA S.p.A.
Address	Via F. Perotti 10 25125 Brescia, Italy
Telephone number	+39 030 2687212
Contact persons	Ms. Silvia Caprini Ms. Elisabetta Zanella E-mail: regulatory.affairs@copangruop.com
Establishment registration #	3002444944
Summary Preparation Date	09th October 2024

2. Subject device

Trade name:	UriSponge™ - Urine Collection, Transport, and Preservation System
Common/Usual name	UriSponge™, Urine Collection, Transport, and Preservation System
Regulation number	21 CFR 866.2390
Regulation name	Transport Culture Medium
Regulatory Class	Class I
Product code	JSM

3. Predicate device

Trade name:	UriSwab™ - Urine Collection, Transport and Preservation System
Common/Usual name	UriSwab™
Regulation number	21 CFR 866.2390, 21CFR 866.2900
Regulation name	Transport Culture Medium
Regulatory Class	Class I
Product code	JSM, LIO
Premarket Notification	K180052
Manufacturer	Copan Italia S.p.A.

4. Device description

Copan's UriSponge™ - Urine Collection, Transport, and Preservation System UriSponge™ 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.

5. Instruction for Use

Copan UriSponge™ - 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, UriSponge™ specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.

The device is intended for prescription use and professional only.

6. Comparison to predicate device

The following table demonstrates the substantial equivalence comparison of UriSponge™ device with its predicate device.

Device & Predicate Device(s):	Device: K232565	Predicate: K180052
Device Trade Name	UriSponge™	UriSwab™
General Device Characteristic Similarities		
Intended Use/Indications For Use	Copan UriSponge™ - 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, UriSponge specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.	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.
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

7. Performance Data

Testing has been performed on UriSponge™ to assess the equivalence of device with chemical preservatives modification to the predicate device, for the suitability of UriSponge™ as sampling and transport system for microbiological urine specimen.

Performance and stability testing, to assess the UriSponge™ ability to preserve microorganism in urine specimen, absence of toxicity if the sponge is not completely saturated and UriSponge™'s ability to maintain its mechanical/physical characteristics, was performed.

Preservative formulation ability to preserve microorganisms:
Performance and stability were evaluated to provide supporting data on preservation of typically found microorganism in urine specimen when urine specimen is collected and transported in UriSponge™ collection device at 2 – 25° C up to 48h throughout UriSponge™ shelf life.

To support the candidate device's performance of preserving microorganisms in urine specimen throughout the claimed shelf-life (i.e., 12 months) of the product, the tests were performed on a set of UriSponge™ lots within one month of manufacture, a set of UriSponge™ lots dated approximately 5 months after manufacture, and a third set of UriSponge™ lots aged beyond 12 months. Pooled human negative clinical urine samples were used as the best representative of the intended use sample type for transport and downstream analysis.

For each UriSponge™ lot and ATCC strains of representative urine microorganism, i.e., *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 cloacae* (ATCC 13047), *Klebsiella pneumoniae* (ATCC 13883) and *Candida albicans* (ATCC 24433). 3 replicates were tested at baseline / time 0 (i.e., T0) and then at 24 hours (T24), at and 48 hours (T48) of sample storage in the cold (2 – 8° C) and room temperature (19 – 25° C). At the end of each incubation period, the devices were centrifuged, the absorbed sample were released, aliquots of sample were spread onto appropriate agar plates, and incubated in appropriate environment for 24-48 hours. Following incubation, colony forming units (CFUs) were determined by counting the colonies and multiplying with appropriate dilution factor. A colony count of 25-250 per plate for at least one dilution and the ΔLog_{10} ≤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 specimen stability.

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

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.
C. albicans (ATCC 24433)	$5x10^2$	2-8°C	-0.02	-0.03
		19-25°C	0.18	0.38
E. coli (ATCC 25922)	$1.5x10^3$	2-8°C	-0.11	-0.20
		19-25°C	-0.11	-0.14
E. faecalis (ATCC 29212)	$7.5x10^2$	2-8°C	-0.19	-0.25
		19-25°C	-0.04	-0.07
P. aeruginosa (ATCC 27853)	$1.5x10^3$	2-8°C	-0.10	-0.16
		19-25°C	-0.20	-0.30
P. mirabilis (ATCC 7002)	$7.5x10^2$	2-8°C	-0.08	-0.05
		19-25°C	-0.10	-0.06
S. saprophyticus (ATCC 15305)	$1.5x10^3$	2-8°C	-0.17	-0.21
		19-25°C	-0.16	0.07
E. cloacae (ATCC 13047)	$1.5x10^3$	2-8°C	-0.23	-0.26
		19-25°C	-0.27	-0.29
K. pneumoniae (ATCC 13883)	$1.5x10^3$	2-8°C	-0.11	-0.06
		19-25°C	-0.21	-0.13
S. agalactiae (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 microorganism 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 (≥ 200 µl), the worst-case scenario for under filling 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 ΔLog_{10} ≤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 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.

Stability of UriSponge™ mechanical/physical characteristics during the device 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 preservative content were evaluated for 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.

8. Conclusions

Copan UriSponge™ demonstrated acceptable stability of the tested representative urine microorganisms (i.e., *C.albicans, E.coli, E.faecalis, P.aeruginosa, P.mirabilis, S.saprophyticus, E.cloacae, K.pneumoniae,* and *S.agalactiae*) when the specimen is stored in the cold (2–8°C) or at room temperature (19–25°C) for up to 48 hours in UriSponge™.

Based on the indications for use, technological characteristics, safety, and performance testing, the candidate device (UriSponge™ with change of chemical preservatives) is substantially equivalent to the legally marketed predicate device, UriSwab™ (K180052).