April 25, 2024

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

Re: K232357
Trade/Device Name: Copan Universal Transport Medium (UTM-RT) System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM, LIO
Dated: March 28, 2024
Received: March 28, 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.

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.

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. (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)*
K232357

Device Name
Copan Universal Transport Medium (UTM-RT) System

Indications for Use *(Describe)*
Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimen containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. UTM-RT can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.
UTM-RT is intended for the stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing respiratory viruses' nucleic acids. UTM-RT is intended for use with compatible molecular assays.

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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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 person	Ms. Silvia Caprini E-mail: regulatory.affairs@copangroup.com
Summary Preparation Date	20th April, 2024

2. Subject device

Trade name	Copan Universal Transport Medium (UTM-RT®) System
Common/Usual name	UTM, UTM-RT, Specimen collection and transport system
Regulation number	21 CFR 866.2390
Regulation name	Transport Culture Medium
Regulatory Class	Class I
Product code	JSM, LIO

3. Predicate device

Manufacturer	Merit Medical System, Inc.
Trade name	Merit Cultura™ Collection and Transport System
Common/Usual name	Specimen collection and transport system
Regulation number	21 CFR 866.2390
Regulation name	Transport Culture Medium
Regulatory Class	Class I
Product code	JSM, LIO
Premarket Notification	K201674

4. Device description

Copan Universal Transport Medium (UTM-RT®) System is composed of a tube with 3mL of UTM-RT® transport medium, which may be supplied in bulk or as a kit with a sterile specimen collection flocked swab. UTM-RT® medium is designed to maintain viability of viruses, chlamydiae, mycoplasma or ureaplasma during transport from the collection site to the testing laboratory for subsequent culture and to maintain the integrity of respiratory viruses' nucleic acids for testing with a compatible molecular assay.

5. Intended Use / Indications for Use

Copan Universal Transport Medium (UTM-RT®) System is intended for the collection and transport of clinical specimen containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. UTM-RT® can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture. UTM-RT® is intended for the stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing respiratory viruses' nucleic acids. UTM-RT® is intended for use with compatible molecular assays.

6. Table 1: Comparison to predicate device

Device & Predicate Devices:	Device (K232357)	Predicate (K201674)
Device Trade Name	Copan Universal Transport Medium (UTM-RT) System	Merit Medical Systems Cultura Collection and Transport System
Manufacturer	Copan Italia S.p.A.	Merit Medical Systems, Inc.
General Device Characteristic Similarities		
Intended Use/Indications For Use	Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimen containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. UTM-RT can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture. UTM-RT is intended for the stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing respiratory viruses' nucleic acids. UTM-RT is intended for use with compatible molecular assays.	The Merit Cultura Collection and Transport System is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic/identification techniques. The Merit Cultura Collection and Transport System is a culture-based media that can be used for upper respiratory viral diagnostic assays including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus.
Tube and cap material	Plastic	Same
Swab material	Various flocked nylon applicators on a plastic shaft with break point	Same
Media Volume	3 mL	Same
Single use device	Yes	Same
Principle of operation	Culture-based medium for maintenance of target microorganism viability and integrity. The specimen can be tested with culture- based technique and with PCR-based technique.	Same
General Device Characteristic Differences		
Shelf-life	18 months	12 months
Media list of ingredients	Hank's Balanced Salt Solution, bovine serum albumin, L-cysteine, gelatin, L-glutamic acid, HEPES buffer, phenol red, sucrose, vancomycin, amphotericin B and colistin	Hank's Balanced Salt Solution (HBSS), Fetal Bovine Serum (FBS), D-glucose, Phenol Red, Gentamicin sulfate and Amphotericin B
Specimen transport conditions and storage time	Up to 96 hours at 2–25°C.	Up to 120 hours at 2–25°C.

7. Non-clinical Performance Data

Culture Performance Study
Data for preservation of viability of microorganisms (i.e., viruses, chlamydiae, mycoplasma, ureaplasma) was included in the original premarket notification (K042970). This part of the Intended Use remains unchanged in the candidate device.

Shelf-life (reagent) stability
Data supporting a shelf-life of 18 months for the UTM-RT medium was accepted for the original premarket notification (K042970) and no variable has further changed in the candidate device.

LoD Verification for Performance and Stability study
LoD for ATCC strains of representative viruses (i.e., Influenza A, Influenza B, Respiratory Syncytial virus) was evaluated to determine the lowest viral amount leading to ≥ 95% of the sample replicates amplified for the viral target. 3xLoD was used for conducting the Performance and Stability study.

Performance and Stability study
Performance and stability were evaluated to provide evidence about preservation of nucleic acids of respiratory viruses when specimen is stored in UTM-RT® at 2–25°C up to 96h throughout UTM-RT® shelf life.

To support the candidate device's performance in preserving viral nucleic acids throughout the claimed shelf-life (i.e., 18 months) for the product, the tests were performed on a set of UTM-RT® lots within one-to-four months of manufacture, a set of UTM-RT® lots dated approximately a year after manufacture, and a third set of UTM-RT® lots aged beyond 18 months (applicable to UTM-RT® tubes with or without glass beads inside).

For each UTM-RT® lot and ATCC strain of representative respiratory viruses (i.e., Influenza A, Influenza B, Respiratory Syncytial virus), 5 replicates were tested at baseline / time 0 (i.e., T_0) and then at 72 hours (T_{72}) and 96 hours (T_{96}) of sample storage in the cold (2–8°C) and room temperature (22–28°C). Tests were performed using the Xpert® Xpress CoV-2/Flu/RSV plus assay in combination with GeneXpert® Dx.

The cycle threshold (Ct) values obtained from the molecular assay were used to assess performance and calculate the difference in Ct values (ΔCt) at tested time points relative to baseline (Time 0). Results were considered acceptable if the ΔCt of < 3 was observed. RSV, Flu A and Flu B target nucleic acids were amplified acceptably with stable ΔCt values relative to baseline after storage in UTM-RT® for up to 96 hours at both room temperature (22–28°C) and refrigerated temperature (2–8°C), demonstrating medium stability during the product shelf life of 18 months, as summarized in Table 2 below.

Table 2: Summary of data demonstrating stability of viral nucleic acids during storage up to 96 hours in UTM-RT®

Virus	Beads	Lot age of UTM-RT at testing*	ΔCt at 96 hrs. ($T_{96} – T_0$) PASS criterion: ΔCt <3			
			2–8°C	Result	22–28°C	Result
Flu A1	UTM-RT® tube With beads or without beads	Freshly produced (new), Middle-Aged, or Old/Expired	0–0.9	PASS	0.3–1.4	PASS
Flu A2			0–0.8	PASS	0.3–1.1	PASS
Flu B			-1–0.4	PASS	-0.8–1	PASS
RSV			-0.4–1	PASS	-0.1–1.1	PASS

*Lot age (in months from production) at testing was in the following range: New (0.8–4.2), Middle-aged (11.1–13.5) and Old/Expired (18.7–22.7).

8. Conclusion

Copan Universal Transport Medium (UTM-RT®) system demonstrated acceptable stability of nucleic acids from representative respiratory viruses (i.e., Influenza A, two (2) targets A1 and A2; Influenza B; Respiratory Syncytial virus) when the specimen is stored in the cold (2–8°C) or at room temperature (20–25°C) for up to 96 hours in UTM-RT® medium.

Based on the indications for use, technological characteristics, safety, and performance testing, the candidate device (Copan Universal Transport Media (UTM-RT®) system) is substantially equivalent to the legally marketed predicate device, Merit Medical Systems Cultura Collection and Transport System (K201674).