May 3, 2023

MedSchenker, Inc.
% Rhonda Alexander
Sr. Consultant, Regulatory Strategy
IUVO Consulting, LLC
PO Box 56436
Virginia Beach, Virginia 23456

Re: K212743
Trade/Device Name: MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport culture medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: December 16, 2022
Received: December 19, 2022

Dear Rhonda Alexander:

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 (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 located 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212743

Device Name
MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System

Indications for Use *(Describe)*
MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is intended for the collection and transport of upper respiratory clinical specimens, containing respiratory viruses, from the collection site to the testing laboratory.
MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is a culture-based medium that can be processed using standard clinical laboratory operating procedures for the recovery of infectious viral particles.

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

Date Prepared: April 25, 2023

1. SUBMITTER

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2. DEVICE

Name of Device:	MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/ SCS30-A) System
Classification Name:	Culture Media, Non-Propagating Transport
Regulatory Class:	Class I
Product Code:	JSM
Regulation:	21 CFR 866.2390

3. PREDICATE DEVICE

Copan Universal Transport Medium (UTM-RT) System (K042970) Manufacturer: Copan Diagnostics Inc.

4. DEVICE DESCRIPTION

The MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System ("MedSchenker STM") aids in the collection and safe transportation of biological samples that will be tested for viruses. MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System provides a universal transport medium for viruses. MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System includes a universal transporting medium that is room temperature stable, which can sustain infectivity of a plurality of clinically important viruses during transit to the testing laboratory. The formulation of the STM includes protein for stabilization, antimicrobial agents to minimize bacterial and fungal contamination, and a buffer to maintain a neutral pH.

The MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is provided in labeled, screw-cap tubes designed for transport of the clinical sample. MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is also supplied as a sample collection kit that

contains one screw-cap tube of STM-RT (room-temperature stable) medium and a peel pouch that contains a sterile specimen-collection swab.

- 1 screw-cap tube containing 1.5mL/2.0mL/3mL of transport medium
- One sterile specimen-collection swab

Configurations to be marketed:

SKU	STM Tube Description	Pack size
STM15-A	1.5 mL Screw cap with Tube	50 Qty
STM20-A	2.0 mL Screw cap with Tube	50 Qty
STM30-A	3.0 mL Screw cap with Tube	50 Qty
SCS30-A	3.0 mL Screw cap with Tube + Nasopharyngeal CavSwab Swabs	50 Qty

5. INDICATIONS FOR USE

MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is intended for the collection and transport of upper respiratory clinical specimens, containing respiratory viruses, from the collection site to the testing laboratory.

MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is a culture-based medium that can be processed using standard clinical laboratory operating procedures for the recovery of infectious viral particles.

6. SUMMARY OF COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices have the following similarities and differences:

Device & Predicate Device(s):	Subject: K212743	Predicate: K042970
Device Trade Name	MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System	Copan Universal Transport Medium (UTM-RT) System
General Device Characteristic Similarities		
Intended Use/Indications For Use	MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is intended for the collection and transport of upper respiratory clinical specimens, containing respiratory viruses, from the collection site to the testing laboratory. MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is a culture-based medium that can be processed using standard clinical laboratory operating procedures for the recovery of infectious viral particles.	Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimens 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.
Media formulation	Amphotericin B Bovine Serum Albumin Hank's Balanced Salt Solution Vancomycin Colistin Gelatin HEPES L-cysteine L-glutamic acid Phenol Red Sucrose	Same
Container for medium	Plastic, conical bottom	Same
Product configuration	Medium Tubes; Kit with Medium Tubes and Swab Option	Same
Storage Temperature	2 - 25ºC (refrigerated and room temperature)	Same
Shelf Life	12 months	Same
Single Use	Yes	Same
General Device Characteristic Differences		
Microorganisms Supported	Viruses: Influenza A (H1N1) Type 5 Adenovirus Herpes Simplex 1 Herpes Simplex 2 Varicella-Zoster Virus	Viruses: Adenovirus Cytomegalovirus (CMV) Echovirus Type 30 (Echo 30) Herpes Simplex Virus Type 1 (HSV1) HSV2 Influenza A Parainfluenza Type 3 Respiratory Syncytial Virus (RSV) Varicella Zoster Virus (VZV) Chlamydiae: *Chlamydia pneumoniae* Strain CM-1 *Chlamydia trachomatis* Type 1 Strain UW-12/UR

		Mycoplasma: *Mycoplasma hominis* *Mycoplasma pneumoniae* Ureaplasma: *Ureaplasma urealyticum*
pH Stability	7.3 ± 0.5 maintained up to 12 months	7.3 ± 0.2 maintained up to 12 months
Swab material	Nylon tip with break point	Polyester

7. PERFORMANCE DATA

The following performance study data were provided in support of the substantial equivalence determination.

Viral recovery studies. Strains of HSV-1, HSV-2, VZV, Flu A, and Adenovirus were used for transport media validation. Each viral strain was mixed with negative nasopharyngeal clinical matrix, followed by a 1:2 dilution with 0.85% saline to obtain diluted viral samples for testing. CavSwabs were used to soak up 100 µL of each concentration of viruses in three replicates. Three replicates of the inoculated swabs were then transferred into tubes with the MedSchenker STM, one swab per tube, and incubated at room temperature (20-25ºC) or refrigerated (4-8ºC) for 0, 24, 48, and 72 hours for HSV-1, HSV-2, and Adenovirus, and for 0 and 24 hours for Flu A and VZV. Each time point was assessed using 3 lots of media. After each time point, the swabs were centrifuged and then removed from the transport media tube and a 50 µL aliquot of the test suspension was seeded onto the appropriate host cell monolayer and incubated at 37ºC (5% CO_2) for 3-5 days. Viral viability was assessed via cytopathic effects (CPE) using the MTT assay. The table below shows the summary and recovery of the 1:2 dilution of each viral strain at the indicated times and temperatures. Viral recovery is represented as $TCID_{50}$/mL and percent change over time.

Summary of recovered viral viability at 4-25ºC

Viral strains		4-8ºC		20-25ºC	
		1:2		1:2	
	Duration (hours)	$TCID_{50}$/mL	Percent change (%) (-ve indicates reduction)	$TCID_{50}$/mL	Percent change (%) (-ve indicates reduction)
HSV-1	**0**	4.77×10^5	0	4.28×10^5	0
	24	4.18×10^5	-12.40	2.87×10^5	-32.91
	48	3.20×10^5	-32.89	4.09×10^5	-4.47
	72	3.32×10^5	-30.30	2.71×10^5	-36.57
HSV-2	**0**	1.49×10^5	0	1.52×10^5	0
	24	1.45×10^5	-2.88	1.24×10^5	-18.60
	48	1.54×10^5	+3.78	1.26×10^5	-14.35
	72	7.56×10^4	-49.24	8.13×10^4	-46.55
Adenovirus	**0**	1.11×10^5	0	1.03×10^5	0
	24	9.95×10^4	-10.72	1.00×10^5	-2.57
	48	9.26×10^4	-16.89	8.76×10^4	-14.62
	72	7.87×10^4	-29.33	5.97×10^4	-41.77
VZV	**0**	1.23×10^6	0	1.08×10^6	0
	24	4.33×10^5	-64.85	1.43×10^6	+32.13

Influenza A	**0**	7.11 x 10^6	0	5.52 x 10^6	0
	24	5.79 x 10^6	-18.57	2.21 x 10^6	-60.05

Conclusion of the culture-based viral recovery study: The MedSchenker STM demonstrated the recovery of HSV-1, HSV-2, and Adenovirus in all replicates at tested incubation times and storage conditions. These data support the transportation of HSV-1, HSV-2, and Adenovirus in MedSchenker STM at refrigerated (4-8ºC) or room temperature (20-25ºC) for up to 72 hours.
The MedSchenker STM also demonstrated the recovery of VZV and Flu A in all replicates at refrigerated (4-8ºC) or room temperature (20-25ºC), up to 24 hours.
The MedSchenker STM was also evaluated for mycoplasma viability at different incubation times and temperatures. Data was insufficient to support use of this medium for transport of specimens for mycoplasma testing

8. CONCLUSION

Based on the indications for use, technological characteristics, safety, and performance testing, the subject device, the MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System, meets the requirements that are considered essential for its intended use and supports a decision of substantial equivalence to a legally marketed device.