510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K212743

B Applicant

MedSchenker, Inc.

C Proprietary and Established Names

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

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

B Measurand:

Not Applicable

C Type of Test:

Non-propagating transport device with culture medium.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Not Applicable

IV Device/System Characteristics:

A Device Description:

The MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System ("MedSchenker STM") includes a universal transport medium that is room temperature stable and that can sustain infectivity of a plurality of clinically important viruses during transit to the testing laboratory. The formulation of the MedSchenker STM includes Hank's Balanced Salt Solution (HBSS) enriched with protein for stabilization, antimicrobial agents to minimize bacterial and fungal contamination, and a buffer system to maintain a neutral pH.

The MedSchenker STM is provided in labeled, screw-cap tubes designed for transport of the clinical sample. MedSchenker STM 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 one sterile nasopharyngeal specimen-collection swab. The MedSchenker STM is provided as follows in Table 1:

Table 1: 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 Swab	50 Qty

B Principle of Operation:

The MedSchenker STM System is used to safely collect, transport, and maintain the viability of clinically important viruses. Intended for use by Health Care Professionals, the transport system allows for the collection of the specimen via the sterile swab, maintenance of viral particles via a buffered salt/serum solution, prevention of microbial overgrowth via antimicrobial agents, as well as a buffer system to maintain a neutral pH. Once the clinical sample is collected, it should be immediately placed in the MedSchenker STM where it is then transported to the laboratory for testing and other detection/identification methods for the presence of a target viruses.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Copan Universal Transport Medium (utm-rt) System

B Predicate 510(k) Number(s):

K042970

C Comparison with Predicate(s):

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	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.

	procedures for the recovery of infectious viral particles.	
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		
Supported claims to perform culture, isolation, and detection of:	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

VI Standards/Guidance Documents Referenced:

1. ISO 11137-2:2013 Sterilization of health care products-Radiation- Part 2: Establishing the radiation dose.

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: The shelf-life of the MedSchenker STM System was determined to be 12 months from the date of manufacture, based on the data provided. The shelf-life of MedSchenker STM System was established using an endpoint real time stability study. Three random samples from each of three non-consecutive lots were assessed using a pH meter at day 0 and day 12 post manufacture and the average pH of all samples analyzed was 7.3 ± 0.5. The pH of the media was again assessed in media stored for 12 months post manufacture and showed a pH average of 7.8 ± 0.3. The media were also assessed for any color change (from pink/violet to any yellowing), or turbidity (any particulates) and no changes were observed at 12 months of storage. The data support a stability claim of 12 months.

   Sterilization: The MedSchenker STM is not provided sterile to the end user. Sterile nasopharyngeal CavSwabs are provided with the MedSchenker STM. The manufacturing process of the swabs includes sterilization by electron beam irradiation set at 15 KiloGray

(kGy) to achieve an SAL of 10^{-6} as confirmed by a bioburden assay in accordance with ISO 11137-2:2013. The manufacturing process of the MedSchenker STM include cleaning by electron beam irradiation to achieve an SAL of 10^{-3} in accordance with ISO 11137-2:2013.

6. Detection Limit:

Performance Testing- Recovery Studies:

Culture-based Viral Recovery Studies:

Stock Preparation. Strains of Herpes Simplex Virus Type 1 and 2 (HSV-1 and 2), Varicella Zoster Virus (VZV), Influenza A 2009 virus (H1N1), and Type 5 Adenovirus were used for media validation. The following cell lines were used for viral recovery: BHκ 21 (for HSV-1 and 2), Vero cells (for VZV), MDCK (for H1N1) and Hep-2 (for Type 5 Adenovirus). The cell lines were grown to near confluency, harvested, diluted in DMEM with 5-10% FBS to obtain a stock solution of 2-3x10^5 cells/mL and plated in microwell plates 24 hours prior to inoculation. The following viral titers were used as the initial stock for the viral recovery studies: HSV-1 (1.32 x 10^6 $TCID_{50}$/mL), HSV-2 (3.47 x 10^5 $TCID_{50}$/mL), VZV (6.31 x 10^6 $TCID_{50}$/mL), H1N1 (1.02 x 10^7 $TCID_{50}$/mL) and Type 5 Adenovirus (1.07 x 10^5 $TCID_{50}$/mL).

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. Table 2 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.

Table 2: 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 x 10^5	0	4.28 x 10^5	0
	24	4.18 x 10^5	-12.40	2.87 x 10^5	-32.91
	48	3.20 x 10^5	-32.89	4.09 x 10^5	-4.47
	72	3.32 x 10^5	-30.30	2.71 x 10^5	-36.57
HSV-2	**0**	1.49 x 10^5	0	1.52 x 10^5	0
	24	1.45 x 10^5	-2.88	1.24 x 10^5	-18.60
	48	1.54 x 10^5	+3.78	1.26 x 10^5	-14.35
	72	7.56 x 10^4	-49.24	8.13 x 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**	7.11×10^6	0	5.52×10^6	0
	24	5.79×10^6	-18.57	2.21×10^6	-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.

Performance of the MedSchenker STM was also evaluated for mycoplasma viability at different incubation times and temperatures. Data was insufficient to support inclusion of mycoplasma in the intended use of the MedSchenker STM. This is reflected in the following labeling limitation:

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.

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 does support a substantial equivalence decision.