510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K240235

B Applicant

Shenzhen Dakewe Bio-engineering Co., Ltd.

C Proprietary and Established Names

OmniTrans Transport 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 OmniTrans Transport System manufactured by Shenzhen Dakewe Bio-engineering Co., Ltd. for the collection and transport of viruses, chlamydiae, mycoplasma, and ureaplasma in clinical specimens for standard diagnostic or identification techniques.

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:

OmniTrans Transport System is intended for use in the collection of clinical specimens (i.e., sputum, throat/oropharyngeal swab, whole blood, urine, skin lesion material or exudate) potentially containing viruses, chlamydiae, mycoplasma, or ureaplasma and in their transport from the collection site to the testing laboratory. The system can be processed using standard clinical laboratory operating procedures for culture of clinical specimens.

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 OmniTrans Transport System is available in the following formats:

(a) Transport medium only, with the medium contained in a labeled plastic screw-cap tube. This format may contain tubes pre-filled with 1 mL, 1.5 mL, 2 mL, or 3 mL of transport medium.

(b) A kit format with the transport medium tube (1 or 3 mL as above) along with one (1) or two (2) swab(s) pre-packaged individually in sterile peel pouch for sample collection. The swab component is available as either or both of two (2) possible swab options:

(i) Minitip flocking swab with 8 cm breaking point.

(ii) Regular flocking swab with 3 cm breaking point.

A specimen bag, with appropriate biosafety warning labels, is also provided with the device for safe transportation of clinical specimens in the transport medium.

The OmniTrans Transport System medium is composed of the following components:

Ingredient	Function
Hank's Balanced Salt Solution	Maintains pH
HEPES	Maintains pH
Bovine Serum Albumin (BSA)	Protein stabilizer
Gelatin	Protein stabilizer
Sucrose	Nutrient component
Amino acid (L-glutamic acid)	Nutrient component
Antibiotics	
Amphotericin B	Inhibits fungi
Vancomycin	Inhibits gram-positive bacteria
Colistin	Inhibits gram-negative bacteria
Phenol red	Indicates pH

The disposable swabs contained in OmniTrans Transport System devices are the only components that may come in contact with patient tissue (e.g., upper respiratory mucosal membranes, i.e., nasopharyngeal, oropharyngeal) during use for typically less than 1 minute. These swabs, manufactured by Shenzhen Dakewe Bio-engineering Co., Ltd. (i.e., the sponsor), are legally marketed standalone devices.

B Principle of Operation:

The candidate device, "OmniTrans Transport 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. The device contains the OmniTrans Transport Medium that is packaged alone or with swabs. Each of the swabs may be used for specimen collection from different anatomical locations. Use of the OmniTrans Transport System is by prescription only, and sample collection is intended to be performed by health care professionals only. Following collection, the specimen is placed into a Transport Medium tube. The candidate device is designed for storage of specimens in the cold (2–8°C) or at controlled room temperatures (20–25°C) for up to 48h. The medium is non-toxic to mammalian host cells or cell lines commonly used for culturing the virus and chlamydiae tested. The system carrying the specimen can be processed using standard clinical laboratory operating procedures for culture of clinical specimens.

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):	Device: K240235	Predicate: K042970
Device Trade Name	OmniTrans Transport System	Copan Universal Transport Medium (UTM-RT) System
Intended Use/Indications For Use	OmniTrans Transport System is intended for use in the collection of clinical specimens (i.e., sputum, throat/oropharyngeal swab, whole blood, urine, skin lesion material or exudate) potentially containing viruses, chlamydiae, mycoplasma, or ureaplasma and in their transport from the collection site to the testing laboratory. The system can be processed using standard clinical laboratory operating procedures for culture of clinical specimens.	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.
General Device Characteristic Similarities		
Single Use Device	Yes	Same
Product Configurations	Medium tubes alone or medium tubes and swabs co-packaged	Same
pH	7.3 ± 0.2	Same
Product Storage temperature	2–25°C	Same
General Device Characteristic Differences		

Device & Predicate Device(s):	Device: K240235	Predicate: K042970
Medium Volume	1 mL; 1.5 mL; 2 mL or 3 mL	1.5 mL; 3 mL; or 10 mL
Container	Tube; plastic; self-standing with a screw cap	Tube; plastic; self-standing with a screw cap; with three 3mm glass beads
Shelf-life	18 months	12 months
Supported strains	• Adenovirus • Cytomegalovirus • Echovirus Type 30 • Herpes Simplex Virus Type 1 • Herpes Simplex Virus Type 2 • Influenza A • Parainfluenza virus type 3 • Respiratory Syncytial Virus • Vaccinia virus • *Chlamydia pneumoniae* • *Chlamydia trachomatis* • *Mycoplasma pneumoniae* • *Ureaplasma urealyticum*	• Adenovirus • Cytomegalovirus • Echovirus Type 30 • Herpes Simplex Virus Type 1 • Herpes Simplex Virus Type 2 • Influenza A • Parainfluenza virus type 3 • Respiratory Syncytial Virus • Varicella Zoster virus • *Chlamydia pneumoniae* • *Chlamydia trachomatis* • *Mycoplasma pneumoniae* • *Ureaplasma urealyticum* • *Mycoplasma hominis*
Medium Formulation	• Hank's Balanced Salt Solution • Bovine Serum Albumin • Gelatin • Sucrose • L-glutamic acid • HEPES buffer • Vancomycin • Amphotericin B • Colistin • Phenol red	• Hank's Balanced Salt Solution • Bovine Serum Albumin • Gelatin • Sucrose • L-glutamic acid • HEPES buffer • Vancomycin • Amphotericin B • Colistin • Phenol red • L-cysteine

VI Standards/Guidance Documents Referenced:

Not Applicable

VII Performance Characteristics:

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; Expected Values (Controls, Calibrators, or Methods); Assay Cut-Off

Not Applicable

6. Shelf-life Stability:

Stability studies were performed in real time with OmniTrans Transport Medium to determine if any quality changes of the transport media occur when stored for extended periods under specified storage conditions (i.e., 2–25ºC). At both cold (2–8ºC) and controlled room temperature (20–25ºC), transport media stability was assessed with serial evaluation of physical, physicochemical, and microbiological characteristics (e.g., medium appearance, net volumetric content; pH; sterility of medium in tube) at media lot production (i.e., time 0) and then at 6, 12, 18 months, and beyond. Further, microbial stasis in medium was compared between a newly produced lot (age 2 months at test) and an older lot (age >18 months at test).

A. Appearance, Net Volumetric Content, and pH:

Random tubes from three (3) medium lots were assessed qualitatively for appearance (color and clarity) and quantitatively through estimation of net volumetric content and pH measurement at time 0 (i.e., 0–2 days after production at ambient temperatures, 20–25ºC) and then serially at 6, 12, 18, and >18 months following storage in the cold (2–8ºC) or at controlled room temperatures (20–25ºC). Additionally, the results from the oldest lots (>18 months of age at test) were compared with those of random tubes from a newly manufactured (day of production) lot. There was no appreciable change in appearance, net volumetric content, or pH of the media in tubes at either temperature range. Further, all pH measurements were within the predefined range (7.3 ± 0.2, i.e., pH 7.1–7.5). Therefore, the predefined acceptance criteria for these physical and physicochemical characteristics were met during storage of the OmniTrans Transport Media for up to 18 months under pre-set storage conditions.

B. Sterility assessment:

The OmniTrans Transport System is not claimed to be sterile nor is it intended to be sterilized by the end user. To decrease the chances of contamination, the screw-capped tubes are separately sterilized with electron beam (e-beam) radiation prior to aseptic filling with transport media under controlled conditions. Using medium lots of serial post-production ages (0, 6, 12, 18, and >18 months), aseptic status of transport media in tubes from these lots was confirmed by observation of no microbial growth after 14 days of incubation of transport medium aliquots in fluid thioglycolate medium at 30–35ºC and trypticase soy broth at 20–25ºC. The swabs provided with the OmniTrans Transport System are individually packaged and are sold as sterile.

C. Cytotoxicity assessment:

The OmniTrans Transport Medium does not come into contact with patient tissue. However, at the destination laboratory, the specimens transported in the medium may be placed in contact with

mammalian cell lines used for viral and chlamydial culture. Therefore, an *in vitro* cytotoxicity assay was conducted for the transport medium with MRC-5, a human fetal lung fibroblast cell-line. Cell viability under test conditions was >70% and the medium did not demonstrate appreciable cytopathic effects on the assayed cells. The assay results were comparable between the oldest (age >18 months) and a newly manufactured (1 month at test) medium lots.

D. Microbial stasis assessment:

Microbial stasis studies were conducted to assess the effectiveness of the antimicrobial components of the OmniTrans Transport Medium. An old (>18 months at test) and a new (<3 months) lot of the medium were tested with one type-culture each of *Staphylococcus aureus*, *Escherichia coli*, and *Candida albicans*. Briefly, each microorganism strain was inoculated in the transport medium to a final concentration of 10^5–10^6 CFU/mL, incubated at 37°C for 0–48 hours, and plated for counting on trypticase soy agar (for bacteria) or Sabouraud's dextrose agar (for *Candida albicans*). The OmniTrans Transport Medium had no increase in microbial counts under the test conditions at 48 hours, and both tested medium lots passed the criteria for microbial stasis.

Conclusions: The collective observations for medium characteristics (i.e., appearance, net volume, pH, sterility in tube, and microbial stasis) in timed studies with variously aged lots support the claim for 18 months of shelf-life stability for the transport medium when stored in the cold (2–8ºC) and at controlled room temperatures (20–25ºC). Therefore, the shelf life of the OmniTrans Transport System was determined to be 18 months from the date of manufacture when stored at temperatures 2–25°C.

7. Performance: Specimen Stability:

Viral and Bacterial recovery studies

Microorganism recovery studies in appropriate negative clinical matrices were conducted with thirteen (13) different representative viruses and bacteria using the OmniTrans Transport Medium lots of various post-production ages, including:

- Old (16–18, or >18 months at the time of use in tests),
- Middle-aged (age 9–10 months at test), and
- New, including <1 week (i.e., newly produced lot) to <3 months of age at test.

Table 1 below summarizes the specimen stability study methodologies and acceptance criteria used for microbial recovery studies. **Table 2** summarizes the negative clinical matrices used to demonstrate the specimen stability. The contrived samples using negative clinical matrix for virus or bacteria in OmniTrans Transport System were stored in the cold (2–8ºC) or at room temperatures (20–25ºC). Microbial recovery studies used media from variously aged lots spanning the claimed shelf life. The recovery study data are summarized in **Tables 3–6** below.

Table 1. Methodology and Acceptance Criteria of Recovery Studies Conducted at cold (2–8ºC) or controlled room (20–25ºC) temperatures.

Method	Acceptance Criteria
• Fluorescent Focus Assay (viruses and chlamydiae) o Neat stocks of organisms prepared in two (2) different dilutions in pooled Negative Clinical Matrix. o Swabs (in triplicate) inoculated with each dilution and incubated in	a. Negative Control (NC): normal cellular morphology observed; no fluorescent foci detected. b. In Positive Control (PC): fluorescent foci detected.

Method	Acceptance Criteria
transport medium at 2–8°C and 20–25°C for the study duration. o Organism viability determined in organism-appropriate culture/growth media at key post-inoculation time points using a 96-well plate culture assay followed by immunostaining and enumeration of fluorescent foci.	c. Test result *invalid* when the criteria are not met in NC/PC groups; identical retests are required. d. Tested organisms recovered at various time points after incubation; a minimum of 48h of testing was considered for recovery results. e. Any change in recovery numbers within one log difference (±90%) was considered acceptable.
• Roll plate assays (qualitative for bacteria) o 10-fold dilution series of inoculum prepared in pooled negative clinical matrix. o Swabs (in triplicate) transferred 100 µL of each dilution into transport medium tubes, which were incubated at 2–8°C or 20–25°C for the study duration. o Swabs removed and rolled directly onto agar plates at key time points after incubation. o Plates incubated 37°C and 5% CO_2 for 6 days for CFU enumeration.	a. In Negative Control (NC): no CFU detected. b. In Positive Control (PC): CFU detected. c. Test result *invalid* when the criteria are not met in NC/PC groups; identical retests are required. d. Tested organisms recovered at various time points after incubation; a minimum of 48h of testing was considered for recovery results. e. There shall be ≥5 CFU following the specified maintenance time from the specific dilution that yielded time-zero plate counts closest to 250 CFU. f. Any change in recovery numbers within one log difference (±90%) was considered acceptable.
• Swab Elution method (quantitative for bacteria) o Inoculum prepared in pooled negative clinical matrix to 1.5×10^7 CFU/mL. o Swabs (in triplicate) spiked with inoculum and incubated in transport medium at 2–8°C and 20–25°C for the study duration. o Swabs removed at key time points after incubation and 10-fold serial dilutions were prepared from each bacterium. • Each dilution (100 µL/dilution) was added onto the agar plate in duplicate and incubated at 37°C and 5% CO_2 for 6 days for CFU enumeration.	a. In Negative Control (NC): no CFU detected. b. In Positive Control (PC): CFU detected. c. Test result *invalid* when the criteria are not met in NC/PC groups; identical retests are required. d. Tested organisms recovered at various time points after incubation; a minimum of 48h of testing was considered for recovery results. e. Any change in recovery numbers within one log difference (±90%) was considered acceptable. f. There shall be no more than a 3 $\log_{10}$ (1×10^3 ± 10%) decline in CFU between the time-zero CFU count and the CFU count of the specified maintenance time. g. For specimens maintained at cold temperature, there should be no more than a one-log increase in CFU and no more than a 3 $\log_{10}$ (1×10^3± 10%) decline in CFU between the time-zero CFU and the CFU after the specified holding period.

Table 2: Summary of all recovery studies performed for various target analytes in appropriate negative clinical matrix (NCM).

Group	Analyte (strain)	NCM used	Recovery Study Data Table #
Virus	Adenovirus (ATCC VR-1)	Sputum	3, 4
	Cytomegalovirus (ATCC VR-977)	Whole blood	3, 4
	Herpes Simplex Virus Type 1 (ATCC VR-260)	Skin lesion exudate	3, 4
	Herpes Simplex Virus Type 2 (ATCC VR-1779)	Skin lesion exudate	3, 4
	Echovirus 30 (ATCC VR-1660)	Throat swab	3, 4
	Vaccinia virus (ATCC VR-1354)	Skin lesion exudate	3, 4
	Influenza A (ATCC VR-1736)	Sputum	3, 4
	Parainfluenza virus type 3 (ATCC VR-1782)	Sputum	3, 4
	Respiratory syncytial virus (ATCC VR-1400)	Sputum	3, 4
Bacteria	*Chlamydia pneumoniae* (ATCC VR-1360)	Sputum	3, 4
	Chlamydia trachomatis (ATCC VR-880)	Sputum	3, 4
	Mycoplasma pneumoniae (ATCC 15531)	Sputum	5, 6
	Ureaplasma urealyticum (ATCC 27816)	Urine	5, 6

Table 3: Recovery of viruses and chlamydiae at 2–8ºC storage.

Test Organism	Average Recovery in Foci Counts/mL ($\times 10^4$ Foci Counts/mL)		% Change in 0–48h (negative value indicates reduction)
	0h	48h	
Adenovirus	2.50	2.48	-1%
Cytomegalovirus	0.95	0.76	-20%
Echovirus 30	1.77	1.04	-41%
Herpes Simplex Virus Type 1	1.02	0.89	-13%
Herpes Simplex Virus Type 2	11.04	6.42	-42%
Vaccinia Virus	11.55	8.30	-28%
Influenza A	13.89	12.21	-12%
Parainfluenza virus type 3	28.84	23.47	-19%
Respiratory Syncytial Virus	5.39	4.76	-12%
Chlamydia pneumoniae	1.33	1.49	12%
Chlamydia trachomatis	1.17	0.56	-52%

Table 4: Recovery of viruses and chlamydiae at 20–25ºC storage.

Test Organism	Average Recovery in Foci Counts/mL ($\times 10^4$ Foci Counts/mL)		% Change in 0–48h (negative value indicates reduction)
	0h	48h	
Adenovirus	2.50	2.64	6%
Cytomegalovirus	0.95	0.51	-46%
Echovirus 30	1.77	0.97	-45%
Herpes Simplex Virus Type 1	1.02	1.09	7%

Test Organism	Average Recovery in Foci Counts/mL ($\times 10^4$ Foci Counts/mL)		% Change in 0–48h (negative value indicates reduction)
	0h	48h	
Herpes Simplex Virus Type 2	11.04	6.52	-41%
Vaccinia Virus	11.55	8.91	-23%
Influenza A	13.89	10.68	-23%
Parainfluenza virus type 3	28.84	8.39	-71%
Respiratory Syncytial Virus	5.39	3.17	-41%
Chlamydia pneumoniae	1.33	1.03	-23%
Chlamydia trachomatis	1.17	0.41	-65%

Table 5: *Mycoplasma pneumoniae* and *Ureaplasma urealyticum* recovery by *Roll-plate* and *Swab elution* method at 2–8°C storage.

Test Organism	Average Recovery in CFU counts using Roll Plate Method			Average Recovery using Swab Elution Method ($\times 10^4$ CFU/mL)		
	0h	48h	% Change in 0–48h (negative value indicates reduction)	0h	48h	Log_{10} Changes in 0–48 hrs. (positive indicates reduction)
Mycoplasma pneumoniae	243	227	-7%	5.96	5.47	0.04
Ureaplasma urealyticum	264	189	-28%	5.10	3.81	0.13

Table 6: *Mycoplasma pneumoniae* and *Ureaplasma urealyticum* recovery by *Roll-plate* and *Swab elution* method at 20–25°C storage.

Test Organism	Average Recovery in CFU counts using Roll Plate Method			Average Recovery using Swab Elution Method ($\times 10^4$ CFU/mL)		
	0h	48h	% Change in 0–48h (negative value indicates reduction)	0h	48h	Log_{10} Changes in 0–48 hrs. (positive indicates reduction)
Mycoplasma pneumoniae	243	187	-23%	5.96	4.14	0.16
Ureaplasma urealyticum	264	139	-47%	5.10	2.68	0.28

Conclusions: The primary criterion for acceptance of recovery studies (as indicated in Table 1) was pre-set at recovered numbers (Fluorescent Foci counts or CFUs, as applicable) being within 1 Log_{10} (i.e., ±90%) of the enumeration at time 0. As observed in the recovery studies using OmniTrans Transport Medium lots of post-production age up to 18 months, all the viral and bacterial recovery counts at 48 hours satisfied this criterion. Therefore, during transport in the OmniTrans Transport System when stored at 2–25°C, the specimen stability claim of microbial recovery for up to 48 hours is acceptable.

B Comparison Studies:

Method Comparison with Predicate Device; Matrix Comparison:

Not Applicable

C Clinical Studies:

Clinical Sensitivity; Clinical Specificity; Other Clinical Supportive Data:

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.