August 19, 2024

Shenzhen Dakewe Bio-engineering Co., Ltd.
Wei Jiang
Deputy General Manager
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Industrial Pk, No.14 Jinhui Rd, Kengzi St, Pingshan District
Shenzhen, Guangdong 518122
China

Re: K240235
Trade/Device Name: OmniTrans Transport System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: July 18, 2024
Received: July 18, 2024

Dear Wei Jiang:

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.

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)*
K240235

Device Name
OmniTrans Transport System

Indications for Use *(Describe)*
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.

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

OmniTrans™ Transport System

1. SUBMITTER

Applicant Name:	Shenzhen Dakewe Bio-engineering Co., Ltd.
Applicant Address:	No.14 Jinhui Road, Kengzi Street, Pingshan District, Shenzhen, Guangdong 518122, CHINA
Contact Person:	Wei Jiang Deputy General Manager
Telephone:	+86-755-86235300
Establishment Registration Number:	3017170972
Date Prepared:	August 18, 2024

2. DEVICE – CLASSIFICATION

Proprietary Name	:	OmniTrans™ Transport System
Common/Usual Name	:	Transport Culture Medium
Classification Name	:	Transport Culture Medium; Culture Media, Non-propagating Transport
Device	:	Non-propagating Transport Device with Culture Medium
Classification Number	:	21 CFR 886.2390
Product Code	:	JSM
Device Class	:	Class I
Review Panel	:	Microbiology

3. PREDICATE DEVICE – CLASSIFICATION

Device Name	:	Copan Universal Transport Medium (UTM-RT) System
510(k) Number	:	K042970
Device	:	Non-propagating Transport Device with Culture Medium
Classification Number	:	21 CFR 886.2390
Product Code	:	JSM
Device Class	:	Class I
Review Panel	:	Microbiology

4. INTENDED USE AND INDICATION FOR USE OF THE DEVICE

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.

5. DEVICE DESCRIPTION

OmniTrans™ Transport System includes a screw-cap tube containing transport medium, which can be supplied alone, or in a kit with one of two possible collection swab options in a sterile peel pouch or with two collection swabs in sterile peel pouches.

The in-tube-only format contains labeled screw-cap tubes pre-filled with 1 mL, 1.5 mL, 2 mL, or 3 mL of transport medium. The in-kit screw-cap tube format is pre-filled with 1 or 3 mL of transport medium for safe transportation of biological specimens.

The format in kit is supplied in pre-packaged collection sets containing one of the two swab types or both of two swab types:
Minitip flocking swab with 8 cm breaking point.
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 different configurations of OmniTrans™ Transport System are provided in table 1.

Table 1. OmniTrans™ Transport System has the following configurations:

<table>
<tr><th rowspan="2">Model</th><th colspan="2">Description</th></tr>
<tr><th>Tube</th><th>Swab</th></tr>
<tr><td rowspan="2">ON</td><td>1 mL of Transport Medium in screw-cap tube</td><td rowspan="2">One minitip flocking swab with 8 cm breaking point</td></tr>
<tr><td>3 mL of Transport Medium in screw-cap tube</td></tr>
<tr><td rowspan="2">OO</td><td>1 mL of Transport Medium in screw-cap tube</td><td rowspan="2">One regular flocking swab with 3 cm breaking point</td></tr>
<tr><td>3 mL of Transport Medium in screw-cap tube</td></tr>
<tr><td rowspan="2">ONO</td><td>1 mL of Transport Medium in screw-cap tube</td><td rowspan="2">One minitip flocking swab with 8 cm breaking point and one regular flocking swab with 3 cm breaking point</td></tr>
<tr><td>3 mL of Transport Medium in screw-cap tube</td></tr>
<tr><td rowspan="4">OM</td><td>3 mL of Transport Medium in screw-cap tube</td><td rowspan="4">Swab not included</td></tr>
<tr><td>2 mL of Transport Medium in screw-cap tube</td></tr>
<tr><td>1 mL of Transport Medium in screw-cap tube</td></tr>
<tr><td>1.5 mL of Transport Medium in screw-cap tube</td></tr>
</table>

6. PRINCIPLE OF OPERATION

The OmniTrans™ Transport System is intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasma or ureaplasma from collection sites to the testing laboratories. The OmniTrans™ Transport Medium is packaged alone or with swabs. Swabs are comprised of an applicator with a solid molded plastic shaft and a flocked tip of either a regular size or a mini size. Each swab is used for specimen collection and placed into a tube of the OmniTrans™ Transport Medium. The swab shaft is snapped off at the pre-scored line (breaking point), and the medium tube is recapped and closed tightly for storage, transportation, and subsequent testing. The specimen can be processed using standard clinical laboratory operating procedures for culture of clinical specimens. Use of the OmniTrans™ Transport System is by prescription only, and sample collection is intended to be performed by health care professionals only. The OmniTrans™ Transport Medium is mainly composed of modified Hank's balanced salt solution, bovine serum albumin, gelatin, sucrose, and amino acid, with HEPES buffer to maintain the pH and phenol red as pH indicator. Antimicrobials are incorporated into the medium to inhibit competing bacteria and fungi. The medium is non-toxic to mammalian host cells or cell lines commonly used for culturing the virus and chlamydiae tested. The OmniTrans™ Transport System is designed for storage of specimens at 2–25℃ for up to 48h.

7. COMPARSION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Side-by-Side Comparison of OmniTrans™ Transport System and Predicate Device

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 Configuration	Medium tubes alone or medium tubes and swabs co-packaged	Same
pH	7.3 ± 0.2	Same
Storage Temperature	2–25℃	Same
General Device Characteristic Differences		
Medium Formulation	Hank's Balanced Salt Solution	Hank's Balanced Salt Solution

Device & Predicate Device(s):	Device: K240235	Predicate: K042970
	Bovine Serum Albumin Gelatin Sucrose L-glutamic acid HEPES buffer Vancomycin Amphotericin B Colistin Phenol red	Bovine Serum Albumin Gelatin Sucrose L-glutamic acid HEPES buffer Vancomycin Amphotericin B Colistin Phenol red L-cysteine
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 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 3 mm glass beads
Shelf-life	18 months	12 months

8. SHELF-LIFE STABILITY

The shelf life for the OmniTrans™ Transport System was determined to be 18 months from the date of manufacture when stored at temperature 2–25°C. The shelf life of the OmniTrans™ Transport System was established in serially conducted real-time aging performance tests at post-production time points T = 0-, 6-, 12-, 18-months, and beyond. The OmniTrans™ Transport Medium was evaluated for appearance, net content, pH value, sterility, and microbial stasis using variously aged lots. Further, recovery studies were conducted with representative viruses and bacteria (see Section 9 for description and data).

a. Appearance, Net content, and pH value:

Stability of appearance was qualitatively assessed by visual inspection with the following criteria: the package should be intact without damage and no leakage of liquid; the media should appear to be a red and transparent without any color change, turbidity, or obvious precipitation. All lots tested at each time point indicated above passed the pre-defined criteria for appearance.

Net content stability was evaluated by measuring the volume of transport medium with the following criterion: the net volumetric content at each time point tested should not be less than the labeled volume.

All the tubes tested at each time point indicated above met the pre-defined criteria for volumetric stability.

The pH stability of the transport medium was determined through testing of five replicates from each lot at each time point indicated above. For all the tubes at each time point, the pH was within the pre-defined pH range of 7.3 ± 0.2.

b. Sterility:

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-cap tubes are sterilized by e-beam irradiation and the transport medium is filled aseptically 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 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. Microbial stasis:

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

9. PERFORMANCE DATA

Performance Testing – Recovery Studies:

Performance of the OmniTrans™ Transport System was evaluated by culture-based recovery studies for representative viruses, chlamydiae, mycoplasma, and ureaplasma in appropriate negative clinical matrices. For viral recovery studies, fluorescent foci count method was utilized to evaluate the recovery of adenovirus (ATCC VR-1), cytomegalovirus (ATCC VR-977), echovirus type 30 (ATCC VR-1660), herpes simplex virus type 1 (ATCC VR-260), herpes simplex virus type 2 (ATCC VR-1779), vaccinia virus (ATCC VR-1354), influenza A (ATCC VR-1736), parainfluenza virus type 3 (ATCC VR-1782), and respiratory syncytial virus (ATCC VR-1400). This method was also utilized to evaluate the recovery of *Chlamydia pneumoniae* (ATCC VR-1360) and *Chlamydia trachomatis* (ATCC VR-880). The recovery of *Mycoplasma pneumoniae* (ATCC 15531) and *Ureaplasma urealyticum* (ATCC 27816) was determined using Roll-Plate Method and Swab Elution Method. Performance evaluations were carried out using old (16–18, or >18 months at test), middle aged (9–10 months at test), and new (<1 week to <3 months at test) lots of the OmniTrans™ Transport Medium.

Negative clinical matrix appropriate for the anatomical localization of respective viral and bacterial infections were obtained. From donors testing negative for respective target pathogens, pooled sputum was used for respiratory pathogens adenovirus, influenza A, parainfluenza virus type 3, respiratory syncytial virus, chlamydiae, and *Mycoplasma pneumoniae*; pooled whole blood, for cytomegalovirus; pooled throat swabs, for the enterovirus echovirus 30; pooled skin-lesion exudates, for vaccinia and herpes simplex virus types 1 and 2; and pooled urine, for *Ureaplasma urealyticum*.

Virus or chlamydial stocks were diluted into two different dilutions in pooled negative clinical matrix and each dilution was transferred with a swab into OmniTrans™ Transport System in triplicate and stored at 2–8ºC or 20–25ºC. Testing was conducted at time zero, 24 hours, and 48 hours. At time points indicated in the Tables 1–4 below following inoculation, each sample was vortexed, and an aliquot was taken for recovery study using suitable tissue culture medium and host cells. For tissue culture, host cells were seeded in a 96-well plate and allowed to adhere for 24–48 hours. MRC-5 cells (SCSP-5040) were used for the recovery test of adenovirus and cytomegalovirus, Vero cells (GNO10) for herpes simplex virus type 1, herpes simplex virus type 2, vaccinia virus and respiratory syncytial virus, LLC-MK2 (GNO6) for parainfluenza virus type 3 and echovirus type 30, and MDCK (GNO23) for influenza A recovery test. For chlamydiae recovery test, Hep-2 cells (ATCC CCL-23) were used for *Chlamydia pneumoniae* and McCoy cells (ATCC CRL-1696) for *Chlamydia trachomatis*.

The transport medium containing virus or chlamydiae was used to inoculate the cell monolayer plate. After incubation, specific immunofluorescent antibody staining was used for detection and enumeration of the viral or chlamydial foci.

The number of infectious particles of viruses and chlamydiae were counted as fluorescent foci and average recovery was calculated as mean of foci count per inoculum volume into 96-well plate (0.05 mL) for each storage temperature and time points. The changes (any increase or decrease) in the recovery between time points (0 to 48 hrs.) were presented in percent values (negative for decrease and positive for increase). Any change that was within one log difference (±90%) was considered acceptable. Results were combined for all the lots irrespective of age as all changes were acceptable. Representative results from the first microbial stock dilution in negative clinical matrix are presented in the following tables:

Table 1: Recovery of viruses and chlamydiae at 2–8ºC storage.

Test Organism	**Average Recovery in Foci Counts/mL (×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 2: Recovery of viruses and chlamydiae at 20–25ºC storage.

Test Organism	**Average Recovery in Foci Counts/mL (×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%
Herpes Simplex Virus Type 2	11.04	6.52	-41%

Test Organism	Average Recovery in Foci Counts/mL (×10^4 Foci Counts/mL)		% Change in 0–48h (negative value indicates reduction)
	0h	48h	
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%

For mycoplasma and ureaplasma recovery studies, inocula were prepared in appropriate negative clinical matrix, and the microbial viability was determined using Roll-Plate Method and Swab Elution Method.

Table 3: Recovery of mycoplasma and ureaplasma at 2–8ºC storage.

Test Organism	Average Recovery in CFU counts using Roll Plate Method			Average Recovery using Swab Elution Method (×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 4: Recovery of mycoplasma and ureaplasma at 20–25ºC storage.

Test Organism	Average Recovery in CFU counts using Roll Plate Method			Average Recovery using Swab Elution Method (×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

As observed in the recovery studies using OmniTrans™ Transport Medium lots of post-production ages up to 18 months, all the viral and bacterial recovery counts (Fluorescent Foci counts or CFUs, as applicable) at 48 hours satisfied the pre-set criterion of being within 1 Log_{10} (i.e., ±90%) of the counts at time 0. Therefore, the OmniTrans™ Transport System demonstrated the recovery of tested viruses, chlamydiae, mycoplasma and ureaplasma at an acceptable rate when the specimen is stored at 2–25ºC for up to 48 hours.

10. CONCLUSION

Based on the intended use/indications for use, technological characteristics, safety and performance testing, the candidate device, OmniTrans™ Transport System, meets the essential requirements for its intended use and is substantially equivalent to the legally marketed predicate device, the Copan Universal Transport Medium (UTM-RT) System.