510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K230035

B Applicant

Shenzhen Dakewe Bio-engineering Co., Ltd.

C Proprietary and Established Names

BioSci Disposable Virus Sampling Tubes

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 a substantial equivalence determination for the BioSci Disposable Virus Sampling Tube for the collection and transport of clinical specimens containing viruses or chlamydiae from the collection site to the testing laboratory.

B Measurand:

Not applicable.

C Type of Test:

Non-propagating Transport Device.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

BioSci Disposable Virus Sampling Tube is intended for the collection and transport of clinical specimens containing viruses or chlamydiae 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:

IV Device/System Characteristics:

A Device Description:

BioSci Disposable Virus Sampling Tube includes a screw-cap tube containing transport medium which is divided into two formats – in kit and tube.

The format in kit is supplied in pre-packaged collection sets containing one of the two swab types:

1. Minitip (2.5 mm tip) flocking swab with 8 cm breaking point, for nasopharyngeal specimen collection
2. Regular (5 mm tip) flocking swab with 3 cm breaking point, for oropharyngeal specimen collection

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

The different configurations of BioSci Disposable Virus Sampling Tube are provided in table 1.

Table 1. BioSci Disposable Virus Sampling Tube has following configurations:

REF	Model	Description	
		Volume	Swab
6991111	VN	1 mL	One minitip flocking swab with 8 cm breaking point
6991311		3 mL	
6991121	VO	1 mL	One regular flocking swab with 3 cm breaking point
6991321		3 mL	
6991191	VNO	1 mL	One minitip flocking swab with 8 cm breaking point and one regular flocking swab with 3cm breaking point
6991391		3 mL	
6991034	VM	1 mL	Swab not included
6991074		1.5 mL	
6991024		2 mL	
6991014		3 mL	

B Principle of Operation:

The BioSci Disposable Virus Sampling Tube is used to safely collect and transport of clinical specimens containing viruses or chlamydiae from collection sites to the testing laboratories. The transport media is packaged alone or with one of two swabs. Swabs are comprised of a solid molded plastic applicator shaft and the tip of the applicator is flocked and either a regular (5 mm) tip or a mini (2.5 mm) tip. After collecting specimens using the swab, the swab is put into the preservation tube for storage and transportation, and subsequent testing. Sample collection is intended to be used by health care professionals. The BioSci Disposable Virus Sampling Tube medium is composed of Hank's balanced salt solution, bovine serum albumin, glucose and the pH are buffered with HEPES buffer. Phenol red is used to indicate pH. Gentamicin and amphotericin B are incorporated into the medium to inhibit competing bacteria and fungi. The medium is isotonic and has been shown to be non-toxic to mammalian host cells.

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: K230035	Predicate: K042970
Device Trade Name	BioSci Disposable Virus Sampling Tube	Copan Universal Transport Medium (UTM-RT) System
General Device Characteristic Similarities		
Intended Use/Indications For Use	BioSci Disposable Virus Sampling Tube is intended for the collection and transport of clinical specimens containing viruses or chlamydiae 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.
Single Use Device	Yes	Same
Product Configuration	Medium Tubes; Kit with Medium Tubes and	Same

	Swab Options	
pH	7.3 ± 0.2	Same
Storage Temperature	2 - 25°C	Same
General Device Characteristic Differences		
Medium Formulation	Hank's Balanced Salt Solution Bovine Serum Albumin Glucose HEPES buffer Amphotericin B Gentamicin 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
Supported Strains	• Adenovirus • Cytomegalovirus • Echovirus Type 30 • Herpes Simplex Virus Type 1 • Herpes Simplex Virus Type 2 • Influenza A • Parainfluenza 3 • Respiratory Syncytial Virus • *Chlamydia pneumoniae* • *Chlamydia trachomatis*	• Adenovirus • Cytomegalovirus • Echovirus Type 30 • Herpes Simplex Virus Type 1 • Herpes Simplex Virus Type 2 • Influenza A • Parainfluenza 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 3mm glass beads
Shelf-life	18 months	12 months

VI Standards/Guidance Documents Referenced:

Not applicable.

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 Stability:
   The shelf life for the BioSci Disposable Virus Sampling Tube was determined to be 18 months from the date of manufacture when stored at temperature 2 – 25°C. The shelf life of the BioSci Disposable Virus Sampling Tube was established using real-time aging performance test at time points T = 0, 3, 6, 9, 12, 15 and 18 months. Three lots of the BioSci Disposable Virus Sampling Tube were evaluated for appearance, net content, pH value, bacteriostasis, sterility and recovery study at each time point in the real-time aging performance test.

   a. Shelf-Life, Appearance, Net content, and pH Value:
      The shelf-life stability was conducted 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 passed the criteria for appearance.

      Net content stability was evaluated by measuring the volume of transport medium. The net content should not be less than the labeled volume. All the tubes tested in time points (1, 3, 9, 12, 15, and 18 months) meet the criteria for volume content. The pH stability of the transport medium was determined through testing of five replicates from each lot at each of the following time points (1, 3, 9, 12, 15, and 18 months). For all the tubes at each time point, the pH was within the predefined pH range of 7.3 ± 0.3.

   b. Sterility:
      The BioSci Disposable Virus Sampling Tube 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 control conditions.

   The results for appearance, net content, and pH value, collectively support the claim for 18 months of storage for the BioSci Disposable Virus Sampling Tube at 2 – 25°C.

6. Detection Limit:

   Performance Testing - Recovery Studies:

Performance of the BioSci Disposable Virus Sampling Tube was evaluated by Culture-Based Recovery Studies for viruses and chlamydiae. For Viral Recovery Studies, Fluorescent Foci Count method was utilized to evaluate the recovery of Adenovirus (ATCC VR-1), Cytomegalovirus (ATCC VR-977), Herpes Simplex Virus Type 1 (ATCC VR-260) and Influenza A (ATCC VR-1736). This method was also utilized to evaluate the recovery of *Chlamydia pneumoniae* (ATCC VR-1360). Performance evaluation was carried out in four lots of media that represent newly manufactured media and older media (about to expire or recently expired).

Virus stocks were diluted into two different dilutions in pooled negative clinical matrix and each dilution was inoculated into swab in triplicate and placed into BioSci Disposable Virus Sampling Tube to store at 2 - 8ºC and 20 - 25ºC for 0 and 48 hours respectively. At each time point 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 Adenovirus and Cytomegalovirus, Vero cells (GNO10) for Herpes Simplex Virus Type 1, and MDCK cells (GNO23) for Influenza A. Aliquot of 100 microliter (µL) virus suspensions prepared in gradient dilutions in triplicate were added on the monolayer plate. After incubation, specific immunofluorescent antibody staining was used for detection. For Chlamydia recovery, McCoy cells (ATCC CRL-1696) were used.

The number of infectious particles 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 timepoints (0 to 48 hr) 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. The results are presented in the Table 2 and 3.

Table 2. Recovery of viruses and Chlamydiae at 4ºC storage.

Test Strain	Average Recovery in Foci count/mL ($\times 10^4$ Foci Counts/mL)		Changes in 0 - 48 hrs. (-ve indicates reduction)
	0 hr.	48 hrs.	
Adenovirus	1.75	2.39	36%
Cytomegalovirus	1.65	1.46	-12%
Herpes Simplex Virus Type 1	1.33	1.56	17%
Influenza A	14.87	4.13	-72%
Chlamydia pneumoniae	15.94	14.75	-7%

Table 3. Recovery of viruses and Chlamydiae at 25ºC storage.

Test Strain	Average Recovery in Foci count/mL ($\times 10^4$ Foci Counts/mL)		Changes in 0 - 48 hrs. (-ve indicates reduction)
	0 hr.	48 hrs.	
Adenovirus	1.75	2.58	47%
Cytomegalovirus	1.65	0.70	-57%
Herpes Simplex Virus Type 1	1.33	1.59	20%
Influenza A	14.87	1.44	-90%

Chlamydia pneumoniae	15.94	13.08	-18%

Conclusion: The BioSci Disposable Virus Sampling Tube demonstrated the recovery of tested viruses at an acceptable rate (Adenovirus, Cytomegalovirus, HSV Type 1 and Influenza A), and *Chlamydia pneumoniae* at 4ºC and 25ºC up to 48 hours. Based on these results, the following statement was added to the package insert.

- Better recovery of viruses and chlamydiae are achieved when specimens are processed shortly after the time of collection and within 48 hours of collection when transported at 4°C compared to 25°C.

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 supports a substantial equivalence decision.