April 5, 2023

Shenzhen Dakewe Bio-engineering Co., Ltd.
Jiang Wei
Deputy General Manager
Room 702-703, Building No.1,Shenzhen Biomedicine Innovations
Industrial Park, No.14 Jinhui Road, Kengzi Street, Pingshan
Shenzhen, Guangdong 518122
China

Re: K230035
Trade/Device Name: BioSci Disposable Virus Sampling Tubes
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: December 20, 2022
Received: January 5, 2023

Dear Jiang Wei:

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.

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 866.9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 866.9.

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.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230035

Device Name
BioSci™ Disposable Virus Sampling Tube

Indications for Use *(Describe)*
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.

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
BioSci™ Disposable Virus Sampling Tube

I. SUBMITTER

Applicant Name:	Shenzhen Dakewe Bio-engineering Co., Ltd.
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Contact Person:	Wei Jiang Deputy General Manager
Telephone:	+86-755-86235300
Establishment Registration Number:	3017170972
Date Prepared:	December 16, 2022

II. DEVICE – CLASSIFIICATION

Proprietary Name	:	BioSci™ Disposable Virus Sampling Tube
Common/Usual Name	:	BioSci™ Viral transport medium (VTM)
Classification Name:		Transport Culture Medium Devices; 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

III. 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

IV. INTENDED USE OF THE DEVICE

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.

V. 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 or both of two swabs 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	

VI. 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.

VII. COMPARSION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Side-by-Side Comparison of BioSci™ Disposable Virus Sampling Tube and Predicate Device

Device & Predicate Device(s):	**Device: K230035**	**Predicate: K042970**
Device Trade Name	BioSci™ Disposable Virus Sampling Tube	Copan Universal Transport Medium (UTM-RT) System
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.
General Device Characteristic Similarities		
Single Use Device	Yes	Same
Product Configuration	Medium Tubes; Kit with Medium Tubes and Swab Options	Same
pH	7.3 ± 0.2	Same
Storage Temperature	2-25℃	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

VIII. 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 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.

b. 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.

c. 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.

IX. PERFORMANCE DATA

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.