January 19, 2023

Shenzhen Dakewe Bio-engineering Co., Ltd.
Wei Jiang
Deputy General Manager
No.14 Jinhui Road, Kengzi Street, Pingshan District
Shenzhen, Guangdong 518122
China

Re: K220059
Trade/Device Name: Biosci™ Inactivated Transport Medium, Biosci™ ITM
Regulation Number: 21 CFR 866.2950
Regulation Name: Microbial Nucleic Acid Storage And Stabilization Device
Regulatory Class: Class II
Product Code: QBD
Dated: December 31, 2021
Received: January 10, 2022

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 (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.

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. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
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)*

K220059

Device Name

Biosci™ Inactivated Transport Medium

Indications for Use *(Describe)*

Biosci™ Inactivated Transport Medium (Biosci™ ITM) is intended for the collection, inactivation, stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing influenza A virus RNA from the collection site to the testing laboratory. The specimen collected in Biosci™ ITM is suitable for use with compatible molecular assays.

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™ Inactivated Transport Medium

I. SUBMITTER

Applicant Name:	Shenzhen Dakewe Bio-engineering Co., Ltd. No.14 Jinhui Road, Kengzi Street Pingshan District Shenzhen, China
Contact Person:	Wei Jiang Deputy General Manager
Telephone:	+86-755-86235300
Establishment Registration Number:	3017170972
Date Prepared:	December 30, 2021

II. DEVICE – CLASSIFIICATION

Proprietary Name	Biosci™ Inactivated Transport Medium
Common/Usual Name	Biosci™ ITM
Device	Transport device for the stabilization of microbial nucleic acids
Classification Number	21 CFR 866.2950
Product Code	QBD
Device Class	Class II
Review Panel	Microbiology

III. PREDICATE DEVICE – CLASSIFICATION

Device Name	eNAT® - molecular collection and preservation medium
510(k) Number	K201849
Device	Transport device for the stabilization of microbial nucleic acids
Classification Number	21 CFR 866.2950
Product Code	QBD
Device Class	Class II
Review Panel	Microbiology

IV. INTENDED USE OF THE DEVICE

Biosci™ Inactivated Transport Medium (Biosci™ ITM) is intended for the collection, inactivation, stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing influenza A virus RNA from the collection site to the testing laboratory. The specimen collected in Biosci™ ITM is suitable for use with compatible molecular assays.

V. DEVICE DESCRIPTION

Biosci™ ITM contains a detergent and a protein denaturant to inactivate Flu A, lyse cells, disrupt lipid membranes, denature proteins and enzymes, and preserve and stabilize influenza A RNA. Therefore, Biosci™ ITM is not intended to be used for culture-based techniques. A specimen bag is also provided for safe transportation of specimens, as well as providing appropriate biosafety warning.

Biosci™ ITM has different configurations:

- A screw-cap tube filled with 1.0, 2.0, or 3.0 mL of Biosci™ ITM
- A screw-cap tube filled with a range of media and package with an oropharyngeal swab for oropharyngeal specimen collection
- A screw-cap tube filled with a range of media and package with a nasopharyngeal swab for nasopharyngeal specimen collection
- A screw-cap tube filled with a range of media and package with a mid-turbinate swab for mid-turbinate specimen collection

VI. COMPARSION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PPREDICATE DEVICE

Biosci™ ITM is substantially equivalent in intended use and overall function to the predicate device eNAT® - molecular collection and preservation medium by Copan Italia S.p.A..

The eNAT® by Copan Italia S.p.A. is provided both in tube and in kit format. The eNAT® tube format is provided ready to use in a screw-cap polypropylene tube containing 2 mL of medium for the inactivation of Flu A and the stabilization of the Flu A virus RNA. The eNAT® kit format consists of media-filled tube with a nylon flocked swab.

The Biosci™ ITM is supplied both in tube and in kit format. The Biosci™ ITM tube format is provided in a screw-cap polypropylene tubes designed for transport of the clinical sample, containing 1, 2, or 3 mL of Biosci™ ITM for the inactivation of Flu A and the stabilization of the Flu A virus RNA. The Biosci™ ITM kit format consists of a pre-filled tube with a nylon flocked swab. The Biosci™ ITM kit will include one of the following swab types: nasopharyngeal swab, oropharyngeal swab or mid-turbinate swab. While the Biosci™ ITM kit is available with three different swab configurations, the predicate device is available with two swab configurations which include nasopharyngeal swab or oropharyngeal swab.

The Biosci™ ITM and eNAT® medium both contain guanidine salt and detergents. These media components inactive Flu A, denature and lyse cells, and stabilize Flu A virus RNA. See Table 1: Side-by-Side Comparison of Biosci™ ITM and Predicate Device.

Table 1: Side-by-Side Comparison of Biosci™ ITM and Predicate Device

Device & Predicate Device(s):	Device: K220059	Predicate: K201849
Device Trade Name	Biosci Inactivated Transport Medium	eNAT molecular collection and preservation medium
Intended Use/Indications For Use	Biosci Inactivated Transport Medium (Biosci ITM) is intended for the collection, stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing influenza A virus RNA from the collection site to the testing laboratory at room temperature. The specimen collected in Biosci ITM is suitable for use with compatible molecular assays.	Copan eNAT- molecular collection and preservation medium- is intended for the stabilization, transportation and inactivation of an unprocessed upper respiratory clinical specimen suspected of containing influenza A virus RNA. eNAT- molecular collection and preservation medium- is intended for use with compatible molecular assays.
General Device Characteristic Similarities		
Single use device	Yes	Same
Specimen types	Upper respiratory specimens	Same
Microorganism nucleic acids preserved	Influenza A virus	Same
Container	Tube; plastic; conical bottom self-standing with a screw cap	Same
Shelf-life	18 months	Same
General Device Characteristic Differences		
Media formulation	-Guanidine hydrochloride -EDTA disodium salt dihydrate -Trisodium citrate dihydrate -Tris -TCEP -HCl -Antifoam A Concentrate -NP-40 -Distilled water	-Tris-EDTA -Guanidine thiocyanate -Detergent -HEPES -Distilled water
Media volume	1, 2, and 3 mL	2 mL
Swabs	Nylon flocked swabs (nasopharyngeal, oropharyngeal and mid-turbinate)	Nylon flocked swabs (nasopharyngeal, oropharyngeal)
Specimen stability	Up to 14 days at 2-25°C	Up to 28 days at 2-25°C
Storage temperature	18-25°C	2-25°C

VII. PERFORMANCE DATA

Limit of Detection:

An analytical sensitivity study was conducted to determine the Flu A virus (H1N1 ATCC VR- 1736) Limit of Detection (LoD) obtained by Biosci™ ITM. The Flu A spiked into negative pooled nasopharyngeal clinical matrix at various concentrations was individually added onto a sterile swab that was added to Biosci™ ITM at a 1:10 dilution. The samples were then processed using a validated RT-PCR assay. The LoD of Biosci™ ITM for Flu A was determined to be 0.2 $TCID_{50}$/mL (Table 2).

Table 2 Summary of results obtained at the dilution corresponding to 0.2 TCID50/mL during the LoD study

	Biosci™ ITM samples
Number of positive replicates	24/24
AVG (Ct value)	35.79
SD (Ct value)	0.67

Viral Stability:

A stability study was designed to demonstrate that RNA from Flu A is preserved and stable in Biosci™ ITM, as well as to demonstrate that the ability to stabilize Flu A RNA is not diminished with the aging of Biosci™ ITM. Flu A was diluted in negative pooled nasopharyngeal clinical matrix at 5× LoD and spotted onto swabs that were incubated in Biosci™ ITM at 1:10 dilution. The samples were then incubated at 2-8°C and 25°C for 0, 7, and 14 days to support a claim of stability for 14 days. The results of Flu A RNA Stability Study with Biosci™ ITM for the claimed 14 days are shown in Tables 3 and 4, which confirmed that Flu A RNA stability in Biosci™ ITM met the pre-defined acceptance criteria of +/- 3.0 Ct value, when compared to day 0. Flu A RNA was stable in newly manufactured, unexpired lots, and lots that have just expired of Biosci™ ITM for up to 14 days when stored at both 2-8°C and 25°C. This study also demonstrates Biosci™ ITM's ability to stabilize Flu A RNA within the claimed 18-month shelf life.

Table 3 Flu A stability in Biosci™ ITM for 14 days at 2-8°C

Days (2-8°C)	0	7	14
AVG (Ct value):	32.26	31.97	31.58
Variation (Ct value):	-	-0.29	-0.68
SD (Ct value):	0.22	0.29	0.31

Table 4 Flu A stability in Biosci™ ITM for 14 days at 25°C

Days (25°C)	0	7	14
AVG (Ct value):	32.20	32.03	31.55
Variation (Ct value):	-	-0.17	-0.65
SD (Ct value):	0.31	0.23	0.28

Inactivation:

An inactivation study was conducted to verify that Biosci™ Inactivated Transport Medium (Biosci™ ITM) inactivates Flu A virus as efficiently as the predicate device.

Flu A at concentrations of 1.2×10^7, 1.2×10^8, and 1.2×10^9 $TCID_{50}$/mL were diluted in negative pooled nasopharyngeal clinical matrix. Each concentration was added to a sterile swab that was then incubated in Biosci™ ITM at a 1:10 dilution for 10, 20, and 30 seconds. Flu A at 1.2×10^3, 1.2×10^4, and 1.2×10^5 $TCID_{50}$/mL were used as control both with and without matrix in the absence of Biosci™ ITM (Table 5). The viability of the virus was measured at each time point after incubation in Biosci™ ITM by inoculating aliquots onto MDCK (Madin-Darby Canine Kidney) cell lines, incubating for four days and measuring the cytopathic effect (CPE).

The results for the inactivation study confirmed >4.0 log reduction in Flu A titer at 10, 20, and 30 seconds incubation in Biosci™ ITM (Table 6), which demonstrates the inactivation performance of Biosci™ ITM is similar to the predicate with regard to Flu A. Also, as noted in the table, CPE was still observed in samples with starting viral concentrations of $\geq10^9$ $TCID_{50}$/mL. Although reduced by ≥5 logs by the Biosci™ ITM, CPE was observed because this high viral concentration exceeds the working range of the cell culture-based assay, and the effect of the inactivation media can no longer be adequately and accurately assessed. Data from the lower viral concentrations were used to assess the inactivation performance, which was acceptable.

Table 5 Flu A Inactivation Study Data Summary for Control Groups

	Preincubation ($TCID_{50}$/mL)	Presence of CPE
Flu A only	1.2×10^5	Yes
	1.2×10^4	Yes
	1.2×10^3	Yes
Flu A and matrix	1.2×10^5	Yes
	1.2×10^4	Yes
	1.2×10^3	Yes
Matrix only	-	No
Biosci™ ITM only *	-	No

Table 6 Flu A inactivation in Biosci™ ITM

Sample	Starting Flu A concentration	10s incubation ($TCID_{50}$ LogΔ）	20s incubation ($TCID_{50}$ LogΔ)	30s incubation ($TCID_{50}$ LogΔ)	Presence of CPE
Flu A, matrix and Biosci™ ITM	1.2×10^9	≥-5.0	≥-5.0	≥-5.0	Yes
	1.2×10^8	>-5.0	>-5.0	>-5.0	No
	1.2×10^7	>-4.0	>-4.0	>-4.0	No

*Biosci™ ITM showed no cytotoxicity on MDCK cells when diluted to 1:1,000.

VIII. CONCLUSIONS

Based on the above, Shenzhen Dakewe Bio-engineering Co., Ltd. has demonstrated that Biosci™ Inactivated Transport Medium is substantially equivalent to the predicate device for collection, stabilization, inactivation and transportation of clinical specimens containing Flu A from the collection site to the testing laboratory. No new issues of safety or effectiveness were found for Biosci™ Inactivated Transport Medium.