December 21, 2023

Hangzhou Genesis Biodetection & Biocontrol Co., Ltd.
Guan Emma, Int'l RA
#139 10th Street (East)
Hangzhou Economic And Technology Development Zone
Hangzhou, 310018, China

Re: K231027
Trade/Device Name: KaiBiLi Extended ViralTrans
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: April 11, 2023
Received: April 11, 2023

Dear Guan Emma:

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,

Natasha Griffin -S

O.B.O. 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231027

Device Name
KaiBiLi Extended ViralTrans

Indications for Use *(Describe)*
The KaiBiLi Extended ViralTrans is intended for the collection and transportation of clinical specimens containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the test site. The KaiBiLi Extended ViralTrans is a culture-based medium that has been validated with multiple sample types and can be used to process clinical specimens using standard laboratory operating procedures for culture of clinical specimens or with other assays that utilize stable recoverable infectious viral particles or bacteria.

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

Dec.18, 2023

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

Submitted by	Hangzhou Genesis Biodetection & Biocontrol Co., Ltd. #139, 10th Street (East), Hangzhou Economic and Technology Development Zone, Hangzhou Zhejiang, CN 310018 Tel：+86-571-87818163
Contact Person	Emma Guan Int'l RA Hangzhou Genesis Biodetection & Biocontrol Co., Ltd. #139, 10th Street (East), Hangzhou Economic and Technology Development Zone, Hangzhou Zhejiang, CN 310018 Telephone: +86 571-86736901-892 Email: yguan@hgb.com.cn
Trade Name	KaiBiLi Extended ViralTrans
Common Name	Transport culture medium
Review Panel	Microbiology
Regulation	21 CFR 866.2390
Class	Class I
Product Code	JSM
Predicate Device	K042970

1. Device Description

The KaiBiLi Extended ViralTrans is room temperature stable and can sustain the viability of virus, chlamydiae, mycoplasma and ureaplasma when transported at 2-8°C or 20-25°C. The product can maintain proper pH environment and inhibit the growth of indigenous microbiota.

KaiBiLi Extended ViralTrans consists of modified Hank's balanced salt solution supplemented with bovine serum albumin, cysteine, glutamic acid, sucrose and HEPES. The HEPES buffer protects against pH changes. Phenol red is used as a pH indicator. Sucrose aids in the preservation of organism viability. To minimize the contamination of commensal organisms, Vancomycin, Econazole Nitrate, and Polymyxin B are incorporated into the medium formula.

2. Intended Use and Indication for Use

The KaiBiLi Extended ViralTrans is intended for the collection and transportation of clinical specimens containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the test site. The KaiBiLi Extended ViralTrans is a culture-based medium that has been validated with multiple sample types and can be used to process clinical specimens using standard laboratory operating procedures for culture of clinical specimens or with other assays that utilize stable recoverable infectious viral particles or bacteria.

3. Device Specification

KaiBiLi Extended ViralTrans is supplied as one plastic flat-bottom vial along with a screw cap for safely containing and transporting biological specimens. The vial is filled with either 1 mL or 3 mL of transport medium and glass beads, or in a kit format together with collection swabs.

The KaiBiLi Extended ViralTrans is offered with one of the following configurations：

Cat. No.	Description
M221001	KaiBiLi Extended ViralTrans 3 mL- 3 mL viral transport medium/vial
M221006	KaiBiLi Extended ViralTrans 3 mL with minitip swab- 3 mL viral transport medium/vial, with a minitip swab
M221007	KaiBiLi Extended ViralTrans 3 mL with regular swab- 3 mL viral transport medium/vial, with a regular swab
M221008	KaiBiLi Extended ViralTrans 3 mL with regular swab and minitip swab- 3 mL viral transport medium/vial, with a regular swab and a minitip swab
M221009	KaiBiLi Extended ViralTrans 1 mL- 1 mL viral transport medium/vial
M221010	KaiBiLi Extended ViralTrans 1 mL with minitip swab- 1 mL viral transport medium/vial, with a minitip swab
M221011	KaiBiLi Extended ViralTrans 1 mL with regular swab- 1 mL viral transport medium/vial, with a regular swab
M221012	KaiBiLi Extended ViralTrans 1 mL with regular swab and minitip swab- 1 mL viral transport medium/vial, with a regular swab and a minitip swab

Media Formulation:

- Hank's Balanced Salts
- HEPES Buffer
- BSA
- L-Cysteine
- L-Glutamic Acid
- Sucrose
- Vancomycin
- Econazole Nitrate
- Polymyxin B
- Phenol Red

4. Substantial Equivalence

The KaiBiLi Extended ViralTrans is compared with the predicate device, K042970, in intended use, medium formulation, product configuration, shelf life, packaging and volume, etc. The safety and effectiveness of the KaiBiLi Extended ViralTrans is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification. Below is a summary of comparison table between KaiBiLi Extended ViralTrans and predicate device K042970:

Device & Predicate Device(s):	Device: K231027	Predicate: K042970
Device Trade Name	KaiBiLi Extended ViralTrans	Copan Universal Transport Medium (UTM-RT) System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The KaiBiLi Extended ViralTrans is intended for the collection and transportation of clinical specimens containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the test site. The KaiBiLi Extended ViralTrans is a culture-based medium that has been validated with multiple sample types and can be used to process clinical specimens using standard laboratory operating procedures for culture of clinical specimens or with other assays that utilize stable recoverable infectious viral particles or bacteria.	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.
Storage Temperature	2-8°C and 20-25°C	Same
Product configuration	Medium tubes; kit with medium tubes and swab options	Same
Single use device	Yes	Same
Container	Tube; plastic; self-standing with a screw cap; with glass beads	Same
Shelf Life	12 months	Same
pH	7.3 +/-0.2	Same

General Device Characteristic Differences		
Media Formulation	Hank's Balanced Salts HEPES Buffer BSA L-Cysteine L-Glutamic Acid Sucrose Vancomycin Econazole Nitrate Polymyxin B Phenol Red	Hank's Balanced Salts Bovine Serum Albumin L-Cysteine Gelatin Sucrose L-Glutamic Acid HEPES Buffer Vancomycin Amphotericin B Colistin Phenol Red
Supported Strains	Adenovirus Cytomegalovirus Herpes Simplex Virus Type 1 Herpes Simplex Virus Type 2 Influenza A Parainfluenza 3 Respiratory Syncytial Virus Varicella Zoster Virus *Mycoplasma pneumoniae* *Chlamydia pneumoniae* *Ureaplasma urealyticum*	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 hominis* *Mycoplasma pneumoniae* *Ureaplasma urealyticum*
Medium volume	1 mL or 3 mL	3 mL or 6 mL

As shown with the comparison above, KaiBiLi Extended ViralTrans and the predicate's specification, safety and performance are comparable.

5. Shelf Life

The shelf life for the KaiBiLi Extended ViralTrans was determined to be 12 months from the date of manufacture when stored at temperature 2-8°C and 20-25°C. The shelf life of the KaiBiLi Extended ViralTrans was established using real-time aging performance test at time points T= 0, 6, 9, 11, and 12 months. Three lots each of the KaiBiLi Extended ViralTrans media at 1 mL and 3 mL configurations (a total of 6 lots) were evaluated. At each time point, appearance, volume, pH, and bacteriostatic performance were assessed.

(1) Appearance and volume
To evaluate appearance, stability of the different lots of KaiBiLi Extended ViralTrans were physically or visually examined. The appearance of the product was observed to be a clear, pink, transparent liquid media with no turbidity or sedimentation. Volume range of 2.7-3.3 mL for the 3 mL media configuration or 0.9-1.1 mL for the 1 mL media configuration were observed. All lots tested at each time point passed the criteria for appearance and net volume.

(2) pH Stability
The pH of the media was used as one of the indicators to support product stability. For all the tubes at each time point and with each lot, the pH was within the targeted pH range of 7.3 ± 0.2 after 12 months of storage.

(3) Bacteriostatic performance
KaiBiLi Extended ViralTrans contains Vancomycin, Econazole Nitrate and Polymyxin B to inhibit growth of bacteria or yeast. At each time point, the KaiBiLi Extended ViralTrans were inoculated with the following microorganisms: *E. Coli* ($1.0x10^3$ CFU/mL), *Staphylococcus aureus* ($1.0x10^3$ CFU/mL), *Streptococcus pyogenus* ($1.0x10^3$ CFU/mL), and *Candida albicans (*$1.0x10^3$ CFU/mL). The KaiBiLi Extended ViralTrans had no microorganism growth after 48 hours growth at 37°C. All lots tested at each time point passed the criteria for bacteriostasis.

6. Performance Testing – Recovery Studies

Performance of the KaiBiLi Extended ViralTrans media was evaluated using culture-based recovery studies for viruses and bacteria at different incubation times and temperatures.

For Recovery Studies, virus titer ($TCID_{50}$/mL) was quantified to evaluate the recovery of the following viruses in the corresponding matrices listed in Table 1 below: Herpes Simplex Virus Type 1 (ATCC VR-733; HSV-1), Herpes Simplex Virus Type 2 (ATCC VR-734; HSV-2), Respiratory Syncytial Virus (ATCC VR-26; RSV), Cytomegalovirus (ATCC VR-977), Adenovirus (ATCC VR-3), Parainfluenza 3 (ATCC VR-93), Influenza A (ATCC VR-822; Flu A), and Varicella Zoster Virus (ATCC VR-1832; VZV). Recovery of *Chlamydophila pneumoniae* (ATCC VR-2282) was evaluated using Fluorescent Foci Count method (IFU/mL). Recovery of *Mycoplasma pneumoniae* (ATCC 15531) and *Ureaplasma urealyticum* (ATCC 27618) was evaluated using the Swab Elution and Roll Plate methods (CFU/mL). Performance evaluation was carried out in three lots of media that represent newly manufactured, middle-aged, and recently expired media. Negative clinical matrix pools were contrived from a minimum of five donors. Matrix pools were determined to be negative prior to use in the specimen stability recovery studies.

Table 1: Negative clinical matrix used for organism validation.

Negative Clinical specimen Type	Microbial Testing
Skin	Herpes Simplex Virus Type 1
Skin	Varicella Zoster Virus
Genital specimens	Herpes Simplex Virus Type 2
Nasopharynx	Respiratory Syncytial Virus
Nasopharynx	Adenovirus
Nasopharynx	Parainfluenza3
Nasopharynx	Influenza A
Throat	*Chlamydophila pneumoniae*
Throat	*Mycoplasma pneumoniae*
Blood	Cytomegalovirus
Urine	Cytomegalovirus
Urine	*Ureaplasma urealyticum*

Viral stocks were diluted into two different dilutions into the corresponding pooled negative clinical matrix and 100 µL of each dilution was transferred onto a dry sterile swab and placed into the KaiBiLi Extended ViralTrans media tubes in triplicate and stored at 2-8ºC and 20-25ºC for 0, 24, and 48 hours. At each incubation time point, the sample was vortexed and a 200µL aliquot was removed for the recovery study. The recovery study was conducted using suitable host cells and tissue culture media. For tissue culture, host cells were plated in a microwell plate and allowed to adhere for 48-72 hours prior to recovery testing. Hep-2 cells were used for HSV-1, RSV, and *C. pneumoniae*; Vero cells were used for HSV-2; MRC-5 cells were used for Cytomegalovirus and VZV; A549 cells were used for Adenovirus; LLC-MK2 cells were used for Parainfluenza 3; MDCK cells were used for Flu A.

Bacterial stocks were diluted into four different dilutions into the corresponding pooled negative clinical matrix and 100 µL of each dilution was transferred onto a dry sterile swab and placed into the KaiBiLi Extended ViralTrans media tubes in duplicate and stored at 2-8ºC and 20-25ºC for 0, 24, and 48 hours. For the swab elution method, at each incubation time point, each sample was vortexed, serially diluted and a 100µL aliquot was removed for the recovery study. The recovery study was conducted using *Mycoplasma pneumoniae* culture medium for *M. pneumoniae* and *Ureaplasma urealyticum* culture medium for *U. urealyticum.* For the roll-plate method, a single dilution was tested in triplicate by streaking the swab from the various KaiBiLi Extended ViralTrans media tube incubation time point over the agar media specified above and incubating for CFU enumeration.

Viral titer for the viruses and foci counts for *C. pneumoniae* were evaluated, and CFU was enumerated for *M. pneumoniae* and *U. urealyticum.* The average recovery was calculated

as mean viral titer ($TCID_{50}$/mL), mean foci count (IFU/mL), or mean CFU/mL, respectively, for each storage temperature and time points. The changes (any increase or decrease) in the recovery between time points (each time point compared to time point 0) were presented in percent values or log_{10} change (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 Tables 2 and 3 below.

Table 2: Recovery of viruses and bacteria at 2-8ºC storage

Test strain	Average recovery ($TCID_{50}$/mL)			Percent observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
HSV-1	$3.53x10^3$	$2.84x10^3$	$2.23x10^3$	-20%	-38%
HSV-2	$4.31x10^3$	$3.54x10^3$	$2.37x10^3$	-18%	-46%
RSV	$1.29x10^4$	$1.13x10^4$	$7.14x10^3$	-14%	-45%
Cytomegalovirus[1]	$5.89x10^3$	$4.75x10^3$	$3.32x10^3$	-19%	-44%
Cytomegalovirus[2]	$5.87x10^3$	$4.76x10^3$	$3.26x10^3$	-19%	-45%
Adenovirus	$1.31x10^5$	$1.06x10^5$	$8.53x10^4$	-20%	-36%
Parainfluenza 3	$2.70x10^4$	$2.19x10^4$	$1.83x10^4$	-19%	-33%
Flu A	$1.46x10^4$	$1.19x10^4$	$9.71x10^3$	-19%	-35%
VZV	$1.25x10^3$	$1.08x10^3$	$7.37x10^2$	-14%	-41%
Test strain	Average recovery (IFU/mL)			Percent observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
C. pneumoniae	$3.40x10^5$	$2.72x10^5$	$2.12x10^5$	-21%	-39%
Test strain	Average recovery using swab elution method (CFU/mL)			Log_{10} observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
M. pneumoniae	$6.36x10^4$	$5.89x10^4$	$2.43x10^4$	-0.03	-0.45
U. urealyticum	$6.74x10^4$	$5.81x10^4$	$2.19x10^4$	-0.08	-0.53
Test strain	Average recovery using roll plate method (CFU)			Log_{10} observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
M. pneumoniae	$2.97x10^2$	$2.18x10^2$	$1.13x10^2$	-0.13	-0.42
U. urealyticum	$2.98x10^2$	$2.11x10^2$	$9.80x10^1$	-0.15	-0.48

[1]Cytomegalovirus recovery in blood; [2]Cytomegalovirus recovery in urine

Table 3: Recovery of viruses and bacteria at 20-25ºC storage

Test strain	Average recovery ($TCID_{50}$/mL)			Percent observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
HSV-1	$3.53x10^3$	$2.83x10^3$	$2.14x10^3$	-21%	-41%
HSV-2	$4.31x10^3$	$3.49x10^3$	$2.30x10^3$	-20%	-48%
RSV	$1.29x10^4$	$1.02x10^4$	$6.76x10^3$	-21%	-48%
Cytomegalovirus[1]	$5.89x10^3$	$4.71x10^3$	$3.22x10^3$	-20%	-45%
Cytomegalovirus[2]	$5.87x10^3$	$4.73x10^3$	$3.07x10^3$	-20%	-48%
Adenovirus	$1.31x10^5$	$1.05x10^5$	$7.89x10^4$	-21%	-41%
Parainfluenza 3	$2.70x10^4$	$2.15x10^4$	$1.78x10^4$	-20%	-35%
Flu A	$1.46x10^4$	$1.17x10^4$	$9.39x10^3$	-20%	-38%
VZV	$1.25x10^3$	$1.04x10^3$	$6.86x10^2$	-17%	-45%
Test strain	Average recovery (IFU/mL)			Percent observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
C. pneumoniae	$3.40x10^5$	$2.69x10^5$	$2.09x10^5$	-21%	-39%
Test strain	Average recovery using swab elution method (CFU/mL)			Log_{10} observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
M. pneumoniae	$6.36x10^4$	$5.92x10^4$	$2.40x10^4$	-0.03	-0.46
U. urealyticum	$6.74x10^4$	$5.60x10^4$	$2.04x10^4$	-0.10	-0.56
Test strain	Average recovery using roll plate method (CFU)			Log_{10} observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
M. pneumoniae	$2.47x10^2$	$2.09x10^2$	$1.03x10^2$	-0.15	-0.46
U. urealyticum	$2.98x10^2$	$1.74x10^2$	$9.40x10^1$	-0.23	-0.50

[1]Cytomegalovirus recovery in blood; [2]Cytomegalovirus recovery in urine

7. Conclusion

The KaiBiLi Extended ViralTrans media demonstrated the recovery of tested viruses (HSV-1, HSV-2, RSV, Cytomegalovirus, Adenovirus, Parainfluenza, Flu A, and VZV) and bacteria (*C. pneumoniae*, *M. pneumoniae*, and *U. urealyticum*) at an acceptable rate when stored at 2-8ºC and 20-25ºC up to 48 hours.

Based on the indications for use, technological characteristics, safety and performance testing, the subject device, the KaiBiLi Extended ViralTrans, meets the requirements that are considered essential for its intended use and is substantially equivalent to the legally marketed predicate device, Copan Universal Transport Medium (UTM-RT) System , K042970.