May 20, 2022

Wuxi Nest Biotechnology Co., Ltd.
℅ Randy Jiang
Senior Technical Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K211256
Trade/Device Name: Disposable Sampler Viral Transport Media
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport culture medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: April 23, 2021
Received: April 26, 2021

Dear Randy 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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

Submitter Information

Company:	Cheng Zhiwei RA Manager Wuxi NEST Biotechnology Co., Ltd. No.530 Xida Road, New District, Wuxi 214112 China Telephone: 0086-510-68006788 Email: project01@nest-wuxi.com
Contact:	Randy Jiang Senior Technical Consultant Emergo Global Consulting, LLC 2500 Bee Cave Road, Building 1, Suite 300 Austin, Texas, 78746, USA Telephone: (512) 327-9997 Fax: (512) 327-9998 LST.AUS.ProjectManagement@ul.com
Date Summary Prepared:	March 29, 2022

Name of the Device

Trade Name:	Disposable Sampler Viral Transport Media
Common Name:	Transport culture medium
Classification Name:	Microbiology
Review Panel:	Microbiology (MI)
Regulation:	866.2390
Class:	Class I
Product Code:	JSM

Equivalence Claimed to Predicate Device

The Disposable Sampler Viral Transport Media is equivalent to the COPAN UNIVERSAL TRANSPORT MEDIUM (UTM-RT) SYSTEM (K042970), manufactured by COPAN DIAGNOSTICS, INC.

Device Description

The Disposable Sampler Viral Transport Media is composed of preservation tubes filled with VTM (Viral Transport Media), kitted with or without swabs, depending on the product type. The Disposable Sampler Viral Transport Media is composed of Sodium chloride, Disodium hydrogen phosphate dodecahydrate, Potassium chloride, Potassium dihydrogen phosphate, Magnesium sulfate heptahydrate, Glucose, HEPES, Sodium bicarbonate, Fluconazole, Gentamicin sulfate, Griseofulvin, Polymyxin sulfate, Phenol red (optional), Sodium hydroxide, Calcium chloride, Bovine serum albumin and L-Cysteine. The preservation tube is made of medical-grade polypropylene materials. For both oropharyngeal and nasopharyngeal swabs, the swab head is made of flocked nylon fiber, and the rod is made of ABS (acrylonitrile butadiene styrene).

Indication for Use Statement

The NEST Disposable Sampler (Viral Transport Medium) is intended for the collection and transport of upper respiratory clinical specimens to the laboratory for standard diagnostic or identification techniques. The Viral Transport Medium can be used in the laboratory to perform culture, isolation and detection of upper respiratory viruses including Influenza A, Rhinovirus, and Respiratory Syncytial Virus (RSV).

Substantial Equivalence Discussion

The following table compares the Disposable Sampler Viral Transport Media to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 1: Subject and Predicate Device Comparison Table

Device & Predicate Device(s):	Device K211256	Predicate K042970
Device Trade Name	NEST Disposable Sampler Viral Transport Media	Copan universal transport medium (UTM-RT) system
General Device Characteristic Similarities		
Intended Use/Indications For Use	The NEST Disposable Sampler (Viral Transport Medium) is	Copan Universal Transport Medium (UTM-RT) System is intended for the collection and

	intended for the collection and transport of upper respiratory clinical specimens to the laboratory for standard diagnostic or identification techniques. The Viral Transport Medium can be used in the laboratory to perform culture, isolation and detection of upper respiratory viruses including Influenza A, Rhinovirus, and Respiratory Syncytial Virus (RSV).	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.
Device Product Code and Classification	JSM, Class I	JSM, Class I
Shelf Life	12 months	12 months
pH	pH 7.3 ± 0.2 at 25ºC	pH 7.3 ± 0.2 at 25ºC
General Device Characteristic Differences		
Media formulation	HANK's Balanced Salts Solution, HEPES, Sodium bicarbonate,	HANK's Balanced Salts, BSA, L-cysteine, gelatin, sucrose, L-

	Fluconazole, Gentamicin sulfate, Griseofulvin, Polymyxin sulfate, Phenol red, Sodium hydroxide, glucose, BSA and L-cysteine.	glutamic acid, HEPES buffer, vancomycin, amphotericin B, colistin, phenol red
Vial Specification	5 mL vial: 2.5 mL VTM 10 mL vial: 3.0 mL VTM	1 mL UTM in 12x80 mm tube 3 mL UTM in 16x100 mm tube 10 mL UTM in 25x90 mm tube
Supported claims to perform culture, isolation and detection of:	Influenza A, Rhinovirus, and Respiratory Syncytial Virus (RSV)	chlamydiae, mycoplasma or ureaplasma and viruses
pH indicator	Optional	None

Non-Clinical Performance Data

Culture-Based Viral Recovery Studies

To demonstrate safety and effectiveness of Disposable Sampler Viral Transport Media and to show substantial equivalence to the predicate device, Wuxi Nest completed the following non-clinical tests. Performance of the NEST Disposable Samplers were evaluated for viral recovery using commercial strains of Influenza A virus A/PR/8/34 H1N1, Rhinovirus Type 16, and Respiratory syncytial virus Type A. A 100µl aliquot of virus culture with 10^6 $TCID_{50}$/ml virus was added into 900µl of different batches of preservation solution (three lots) with negative clinical nasopharyngeal matrix collected from healthy subjects. After mixing, the samples were then stored at 23-25 ℃ (room temperature) and 2-8 ℃ (refrigerated) for 0, 24, and 48 hours. Different lots of preservation solution without virus dilution were used as controls with negative

clinical nasopharyngeal matrix collected from healthy subjects. At each timepoint, an aliquot of the preservation solution, matrix and organism suspension was inoculated into the appropriate host cell line. Finally, the number of plaques formed on the host cells by the recovered viable virus were calculated. All the cultures were processed using standard laboratory culture techniques. Each time point was assessed in triplicate and the average value was taken as the final value. The results of the viral recovery studies are represented in Table 2 below and show the attenuation rate of the viruses tested at different temperatures and times.

Table 2: Viral viability study results

The test virus	Test samples (Lot No.)	Test conditions	Mean Virus Titer ($x10^4$ PFU/mL)	Attenuation rate (%)
Influenza A virus A/PR/8/34 H1N1	080921ES1	0h	83.4	-
		4°C, 24h	70.5	15.47
		4°C, 48h	61.3	26.50
		25°C, 24h	66.4	20.38
		25°C, 48h	44.7	46.40
	040121PS	0h	79.2	-
		4°C, 24h	71.8	9.34
		4°C, 48h	63.7	19.57
		25°C, 24h	66.9	15.53
		25°C, 48h	44.4	43.94
	101020E01	0h	92.3	-
		4°C, 24h	79.1	14.3
		4°C, 48h	73.5	20.37
		25°C, 24h	74.3	19.50
		25°C, 48h	60.2	34.78
Rhinovirus Type 16	080921ES1	0h	231.7	-
		4°C, 24h	213.8	7.73
		4°C, 48h	204.5	11.74
		25°C, 24h	168.5	27.28
		25°C, 48h	124.7	46.18
	040121PS	0h	203.7	-
		4°C, 24h	183.4	9.97

		4°C, 48h	169.3	16.89
		25°C, 24h	200.2	1.72
		25°C, 48h	157.8	22.53
	101020E01	0h	176.5	-
		4°C, 24h	169.8	3.80
		4°C, 48h	154.3	12.58
		25°C, 24h	114.0	35.41
		25°C, 48h	93.8	46.86
Respiratory syncytial virus Type A	080921ES1	0h	26.8	-
		4°C, 24h	22.0	17.91
		4°C, 48h	20.0	25.37
		25°C, 24h	23.2	13.43
		25°C, 48h	21.0	21.64
	040121PS	0h	31.0	-
		4°C, 24h	24.0	22.58
		4°C, 48h	21.2	31.61
		25°C, 24h	24.8	20.00
		25°C, 48h	16.2	47.74
	101020E01	0h	33.5	-
		4°C, 24h	26.3	21.49
		4°C, 48h	25.7	23.28
		25°C, 24h	23.8	28.96
		25°C, 48h	26.7	20.30

The NEST Disposable Samplers preserved the samples of all the viruses tested for up to 48 hours at both room temperature and when refrigerated. The results confirm that the media stabilizes the target viruses meeting the performance specifications for the subject device.

Statement of Substantial Equivalence

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