April 11, 2024

C/O Katrina Fiedler
Founder & Principal Consultant
WolfKat Regulatory Consulting, LLC.
44 Oxford Drive
East Winsor, New Jersey 08520

Re: K202531
Trade/Device Name: Azer Scientific Universal Transport Medium
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: August 31, 2020
Received: September 1, 2020

Dear Katrina Fiedler:

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
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)*

K202531

Device Name

Azer Scientific Universal Transport Medium

Indications for Use *(Describe)*

The Azer Scientific Universal Transport Medium is for the collection and transport of upper respiratory clinical specimens, containing respiratory viruses from the collection site to the testing laboratory. The Azer Scientific Universal Transport Medium is a culture-based media that can be processed using standard clinical laboratory operating procedures for the isolation and detection of upper respiratory viruses including Influenza A, Respiratory Syncytial Virus (RSV) and Adenovirus.

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 – K202531

April 10, 2024

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

Submitted by:	Azer Scientific, Inc. 701 Hemlock Road Morgantown PA 19543 Tel: +1-610-524-5810 E-mail: info@AzerSci.com Website: www. AzerSci.com
Contact Person:	Katrina Fiedler, Founder and Principal Consultant, WolfKat Regulatory Consulting, LLC. 44 Oxford Drive East Winsor, NJ 08520 Tel: +1-609-902-6162 Email: admin@wolfkatreg.com Website: www.wolfkatreg.com
Name of Device:	Azer Scientific Universal Transport Medium
Classification Name:	Culture Media, Non-Propagating Transport
Regulatory Class:	Class I
Product Code:	JSM
Regulation:	21 CFR 866.2390
Predicate Device:	Copan Universal Transport Medium (UTM-RT) System (K042970) Manufacturer: Copan Diagnostics Inc.

1. Intended Use/Indication for Use

The Azer Scientific Universal Transport Medium is for the collection and transport of upper respiratory clinical specimens, containing respiratory viruses from the collection site to the testing laboratory. The Azer Scientific Universal Transport Medium is a culture-based media that can be processed using standard clinical laboratory operating procedures for the isolation and detection of upper respiratory viruses including Influenza A, Respiratory Syncytial Virus (RSV) and Adenovirus.

2. Device Description

The Azer Scientific Universal Transport Medium includes a plastic screw-cap tube with conical bottom containing 3 mL of transport medium and three, 3 mm size glass beads. Azer Scientific Universal Transport Medium tubes can be supplied alone or in a kit format with one of three different collection swab options in a sterile peel pouch.

Swab Options:

- PurFlock Ultra 6" Sterile Standard Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Regular Flock Tipped Specimen Collection Applicator and Plastic Handle (80mm Breakpoint) (SKU#: 25-3306-U).
- PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Revised Ultrafine Flock Tipped Applicator with Plastic Handle (80mm breakpoint) (SKU#: 25-3320-U EMB 80MM)
- Azer Scientific 3" Foam Swab, individually wrapped, sterile (ES45019S)

The Azer Scientific Universal Transport Medium is offered in the following configurations**:**

SKU	PRODUCT DESCRIPTION		PACKAGING
	TUBE	SWAB	
PFUTM-10	3 mL universal transport medium in 10mL screw cap tube with internal shaped conical bottom with 3 mm size glass beads	NA	50/Pack
PFUTM-15	3 mL universal transport medium in 15mL screw cap tube with internal shaped conical bottom with 3 mm size glass beads	NA	50/Pack
ES45019S	NA	Azer Scientific Foam Swab, individually wrapped, sterile	500/pack
NPKIT-10	PFUTM-10	PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Revised Ultrafine Flock Tipped Applicator with Plastic Handle (80mm breakpoint)	50/pack
MCKIT-10	PFUTM-10	PurFlock Ultra 6" Sterile Standard Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Regular Flock Tipped Specimen Collection Applicator and Plastic Handle (80mm Breakpoint)	50/pack
FOAMKIT-10	PFUTM-10	3" Foam Specimen Collection Swab	50/pack

NPKIT-15	PFUTM-15	PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Revised Ultrafine Flock Tipped Applicator with Plastic Handle (80mm breakpoint)	50/pack
MCKIT-15	PFUTM-15	PurFlock Ultra 6" Sterile Standard Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Regular Flock Tipped Specimen Collection Applicator and Plastic Handle (80mm Breakpoint)	50/pack
FOAMKIT - 15	PFUTM-15	3" Foam Specimen collection Swab	50/pack

Media Formulation:

- Hank's Balanced Salt Solution
- Bovine Serum Albumin
- L-cysteine
- Gelatin
- Sucrose
- L-glutamic acid
- HEPES buffer
- Vancomycin
- Amphotericin B
- Colistin
- Phenol red

3. Principles of Operation

The Azer Scientific Universal Transport Medium is an isotonic and non-toxic medium. The medium consists of the following: Hank's Balanced Salt Solution. Bovine Serum Albumin, L-cysteine, L-glutamic acid, Vancomycin, Amphotericin B, Colistin, gelatin, HEPES Buffer, sucrose and Phenol red. The Hank's buffer creates a neutral environment to help increase the stability of the virus. Bovine Serum Albumin (BSA) acts as a protein stabilizer by forming a protective film on the protein shell of the virus, making it less likely to break down and ensuring the integrity of the virus. Vancomycin, Amphotericin B, and Colistin inhibit the proliferation of competing bacteria and yeasts. L-glutamic acid serves as an auxiliary energy source to keep cell and virus stability. HEPES buffer provides additional help to maintain a stable pH. Phenol red is

a pH indicator which serves as a visual quality control mechanism. The L-cysteine, gelatin, and sucrose, helps in preserving the virus.

4. Substantial Equivalence

The Azer Scientific Universal Transport Medium 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 Azer Scientific Universal Transport Medium is adequately supported by the substantial equivalence information and testing results provided. Below is a summary of comparison table between Azer Scientific Universal Transport Medium and the predicate device, K042970:

Device & Predicate Device(s):	Device: K202531	Predicate: K042970
Device Trade Name	Azer Scientific Universal Transport Medium	Copan Universal Transport Medium (UTM-RT) System
General Device Characteristic Similarities		
Intended Use/Indications for Use	The Azer Scientific Universal Transport Medium is for the collection and transport of upper respiratory clinical specimens, containing respiratory viruses from the collection site to the testing laboratory. The Azer Scientific Universal Transport Medium is a culture-based media that can be processed using standard clinical laboratory operating procedures for the isolation and detection of upper respiratory viruses including Influenza A, Respiratory Syncytial Virus (RSV) and Adenovirus.	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.
Single-use Device	Yes	Same

Medium Formulation	Hank's Balanced Salt Solution Bovine Serum Albumin L-cysteine Gelatin Sucrose L-glutamic acid HEPES buffer Vancomycin Amphotericin B Colistin Phenol red	Same
pH	7.3 ± 0.2	Same
Storage Temperature	2 – 25°C	Same
Glass Beads	3 x 3 mm	Same
Container	Plastic, conical bottom	Same
Product Configuration	Media in tube with cap or Media Kit; Media in tube with cap and sterile swab options	Same
Shelf Life	12 months	Same
General Device Characteristic Differences		
Fill volume	3 mL	1.5 mL; 3 mL; or 10 mL
Swab Tip	Flocked Nylon (Specimen Collection and NP Swabs) Reticulated Polyurethane Foam (Mid-turbinate Foam Swab)	Polyester
Swab Shaft	Polypropylene (Specimen Collection, NP, and Foam Swabs)	Plastic; Stainless Steel - Plastic

Supported Strains	**Viruses:** Influenza A Adenovirus Respiratory Syncytial Virus (RSV)	**Viruses:** Adenovirus Cytomegalovirus (CMV) Echovirus Type 30 (Echo 30) Herpes Simplex Virus Type 1 (HSV1) HSV2 Influenza A Parainfluenza Type 3 Respiratory Syncytial Virus (RSV) Varicella Zoster Virus (VZV) **Chlamydiae:** *Chlamydia pneumoniae Strain CM-1* *Chlamydia trachomatis Type 1 Strain UW-12/UR* **Mycoplasma:** *Mycoplasma hominis* *Mycoplasma pneumoniae* **Ureaplasma:** *Ureaplasma urealyticum*
Sample Stability	48 hrs. at 2-8°C or 20-25°C	48 hrs. at 4°C or 20-25°C

5. **Shelf-life Stability**

The shelf-life of the Azer Scientific Universal Transport Medium was determined to be 12 months from the date of manufacture when stored at 2-25°C. Three lots of Azer Scientific Universal Transport Medium were assessed qualitatively at each time point for functionality and physical characteristics using real time ageing studies. In the real time study, media lots were held at 2-8°C, and 20-25°C for 12 months (T=0, 3, 6, 9, and 12 months).

a) Appearance

To evaluate appearance, the different lots of the Azer Scientific Universal Transport Medium were visually examined. The appearance of the product was observed to have no significant color change (pink, transparent), precipitate, particulates, or cloudy appearance. All lots tested at each time point passed the criteria for appearance when held at 2-8°C, and 20-25°C.

b) 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 each lot, the pH was within the targeted range of 7.3±0.2 when held at 2-8°C and 20-25°C only.

c) Microbial contamination check
Microbial contamination was determined by incubating an appropriate number of Azer Scientific Universal Transport Medium lots overnight at 37±2°C and examined for growth contaminants. All lots tested at each time point and each temperature passed the criteria for no contamination (no growth) when held at 2-8°C, and 20-25°C.

6. Sterility

The Azer Scientific Universal Transport Medium is not claimed to be sterile nor is it intended to be sterilized by the end user. To decrease the chances of contamination, components of the Azer Scientific Universal Transport Medium are either sterilized by moist heat sterilization or filter sterilization and the transport medium is filled aseptically under controlled conditions. The swabs provided with the Azer Scientific Universal Transport Medium are individually packaged and are sold as sterile.

7. Performance Data

Performance Testing - Viral Recovery:
Performance of the Azer Scientific Universal Transport Medium was evaluated by performing culture-based recovery studies. The viral recovery study was conducted by spiking virus stock Influenza A/Puerto Rico-8-9VMC2/1934 (H1N1), Human Adenovirus 10 JJ (AV), and Human Respiratory Syncytial Virus, Strain A1998/3-2 (HRSV) into pooled, human nasopharyngeal swab sample matrix tested as negative using an FDA cleared RT-PCR assay.

Performance evaluation was carried out using three (3) lots of test kits each including a PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/Polystyrene Handle, 80 mm Breakpoint swab provided with Azer Scientific Universal Transport Medium with serial dilutions of each virus (10^{-1}, 10^{-2}, 10^{-3} and 10^{-4}) spiked into negative clinical matrix in triplicate. Contrived samples were held at both 2-8ºC and 20-25 ºC for 0, 24, and 48 hours in a 96-well plate.

Samples in the 96-well plate were examined under the microscope for cytopathic effect (CPE) after the appropriate incubation period for each virus time point. Viral titers of samples collected at 0, 24, and 48 hours were calculated for recovery and determined by percent log reduction of TCID50/mL using the Reed-Muench method. Host cell lines used for the different viruses are outlined in **Table 1**. Viral Recovery study data is outlined in **Table 2**. Any change of virus titer that was within one log (+/-90%) from the baseline (time point 0) was considered acceptable.

Table 1: Host Cells

Organism	Strain ID	Host Cell/Growth Medium
Influenza A/Puerto Rico-8-9VMC2/1934 (H1N1)	NR-29027	MDCK cells/EMEM + 10% FBS
Human Adenovirus 10 JJ (AV)	NR-53907	A549 cells/EMEM + 10% FBS
Human Respiratory Syncytial Virus, Strain A1998/3-2 (HRSV)	NR-28529	HEP-2 cells/EMEM + 10% FBS

Table 2: Viral Recovery

Viral Strain	Duration (hrs.)	2-8°C		20-25°C	
		Average $TCID_{50}$/mL	Average Percent Change (- is a reduction)	Average $TCID_{50}$/mL	Average Percent Change (- is a reduction)
Influenza A/Puerto Rico-8-9VMC2/1934 (H1N1)	0	4.74×10^3	N/A	4.74×10^3	N/A
	24	11.03×10^3	133%*	8.76×10^3	85%
	48	8.38×10^3	77%	6.69×10^3	41%
Adenovirus 10 JJ (AV)	0	22.43×10^3	N/A	22.43×10^3	N/A
	24	14.30×10^3	-36%	39.47×10^3	76%
	48	9.53×10^3	-58%	13.94×10^3	-38%
Human Respiratory Syncytial Virus (HRSV)	0	16.48×10^3	N/A	16.48×10^3	N/A
	24	10.01×10^3	-39%	15.50×10^3	-6%
	48	16.47×10^3	-0%	12.63×10^3	-23%

*Considered acceptable because subsequent timepoint, i.e., 48 h time points showed $\leq$ 90% increase.

Conclusion of the culture-based viral recovery study:
The Azer Scientific Universal Transport Medium demonstrated the recovery of H1N1 Influenza BEI NR-29027, Adenovirus 10 JJ, and Human Respiratory Syncytial Virus (HRSV) in all replicates at tested incubation times and storage conditions met the acceptance criteria. This data supports the transportation of Influenza A, Adenovirus, and Respiratory Syncytial Virus (RSV) in Azer Scientific Universal Transport Medium when stored refrigerated (2-8°C) or room temperature (20-25°C) for up to 48 hours.

8. Conclusion

Based on the indications for use, technological characteristics, safety, and performance testing, the subject device, Azer Scientific Universal Transport Medium 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.