July 15, 2024

Hanchang Medic Co., Ltd. (Han Chang Medic)
Hyunsoo Shin
Official Correspondent
10, Wolsan-ro 201beon-gil, Eumbong-myeon
Asan-Si, Chungcheognam-Do 14501
Korea, South

Re: K233449
Trade/Device Name: Avantik VTM
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: June 10, 2024
Received: June 10, 2024

Dear Hyunsoo Shin:

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,

Ribhi Shawar -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233449

Device Name
Avantik VTM

Indications for Use *(Describe)*
The Avantik VTM is intended for the collection and transport of upper respiratory clinical specimens containing respiratory viruses, from the collection site to the testing laboratory. The collection system is a culture-based media that is intended to be used with standard laboratory examination, culture or with other assays that utilize stable recoverable infectious viral particles.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

This summary of 510(k) substantial equivalence information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER: HanChang Medic Co. Ltd. (HAN CHANG MEDIC)
Address: 10, Wolsan-ro 201beon-gil, Eumbong-myeon, Asan-si, Chungcheongnam-do, Republic of Korea
Tel: +82-41-547-8805
Fax: N/A

Contact Person: Shin, Hyunsoo

Date Prepared: JUL-8-2024

II. DEVICE

Device Trade Name:	Avantik VTM
Classification Name:	CULTURE MEDIA, NON-PROPAGATING TRANSPORT
Regulation:	21 CFR §866.2390
Regulatory Class:	Class I
Device Panel:	MICROBIOLOGY
Product Classification Code:	JSM

III. PREDICATE DEVICE

Predicate Manufacturer:	Medschenker, Inc.
Predicate Trade Name:	MedSchenker Smart Transport Medium (STM15-A/STM20A/STM30-A/SCS30-A) System
Predicate 510(k):	K212743

IV. DEVICE DESCRIPTION

The Avantik VTM is a Non-Propagating Transport Medium Device designed to facilitate the secure collection and transportation of biological samples for diagnosing viral infections. The device contains a transport medium that maintains the viability and infectivity of clinically significant viruses en route to testing laboratories.

The device can be stored between 2 - 25°C for up to 12 months and is only for use by Health Care Professionals. Upon collection, samples should be immediately placed in the transport tube to maintain optimal conditions. It is recommended to refrigerate the samples between 2 - 8°C or store them on wet ice to maintain a temperature of 2 - 8°C during transit. Post-collection, the specimen can be transported at 2 - 25°C and should be processed within 48 hours.

The transport system allows for specimen collection, maintenance through a buffered medium, and contains a pH indicator. The liquid medium consists of a mixture of Hank's balanced salt

solution, BSA (Bovine Serum Albumin), L-cysteine, Gelatin, Sucrose, L-glutamic acid, HEPES, Vancomycin, Amphotericin B, Colistin, and Phenol Red. The liquid medium inhibits the growth of competing bacteria and fungus, is non-toxic to mammalian host cells, and supports viral viability during transportation. The device includes a conical polypropylene vial filled with 3 ml of culture medium, secured with a high-density polyethylene screw-on cap.

V. INTENDED USE

The Avantik VTM is intended for the collection and transport of upper respiratory clinical specimens containing respiratory viruses, from the collection site to the testing laboratory. The collection system is a culture-based media that is intended to be used with standard laboratory examination, culture or with other assays that utilize stable recoverable infectious viral particles.

VI. COMPARISON WITH THE PREDICATE DEVCE

The subject and predicate devices have the following similarities and differences:

Device & Predicate Device(s):	**Subject Device: K233449**	**Predicate Device: K212743**
Device Trade Name	Avantik VTM	MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Avantik VTM is intended for the collection and transport of upper respiratory clinical specimens containing respiratory viruses, from the collection site to the testing laboratory. The collection system is a culture-based media that is intended to be used with standard laboratory examination, culture or with other assays that utilize stable recovery of infectious viral particles.	MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is intended for the collection and transport of upper respiratory clinical specimens, containing respiratory viruses, from the collection site to the testing laboratory. MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is a culture-based medium that can be processed using standard clinical laboratory operating procedures for the recovery of infectious viral particles.
Product Code and Classification	JSM, Class I	Same

Media Formulation	• Amphotericin B • Bovine Serum Albumin • Hank's Balanced Salt Solution • Vancomycin • Colistin • Gelatin • HEPES • L-cysteine • L-glutamic acid • Phenol Red • Sucrose	Same
Container for medium	Plastic, conical bottom	Same
Storage Temperature	2 - 25°C (refrigerated and room temperature)	Same
Shelf Life	12 months	Same
pH Stability	7.3 ± 0.5 maintained up to 12 months	Same
Single Use	Yes	Same
General Device Characteristic Differences		
Supported Viruses	Validated Viruses: Influenza A (H3N2) RSV Human Coronavirus	Validated Viruses: Influenza A (H1N1) Type 5 Adenovirus Herpes Simplex 1 Herpes Simplex 2 Varicella-Zoster Virus
Swab Material	Not Applicable	Nylon tip with breakpoint
Product Configuration	Medium Tubes	Medium Tubes; Kit with Medium Tubes and Swab Option
Sample Stability	48 hours	72 hours for HSV-1, HSV-2, and Adenovirus 24 hours for IFA and VZV

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Reagent Stability Study Results

Shelf-life was determined using the data from real-time aged, stability testing of the finished

product at documented intervals. Testing was also performed on lots returning from the simulated distribution per ASTM D4169-16/D4332 testing to determine whether the product maintains acceptable stability under known, stressed shipping conditions. Selected lot samples were assessed by visual inspection, weight, pH, and contamination checks to determine whether lots remained stable at each timepoint. All samples from all lots under all testing conditions gave passing results for all acceptance criteria. The shelf-life of the product was determined to be 12 months from the date of manufacture, based on the data provided.

Viral Recovery Study Results

Performance of the subject device was evaluated in culture-based viral recovery studies in accordance with CLSI M40-A2. Three viral strains were evaluated: influenza A, RSV, and Human Coronavirus NL63 at different incubation times and storage temperatures. Virus viability was then determined after storing in virus transport media for 0 and 48 h at 4°C and a controlled room temperature of 22°C. Three lots of the candidate device were evaluated to validate performance over shelf-life. Percentages of reduction in virus infectivity following storage in VTM compared to Time 0 are shown in the table below. The device demonstrated recovery of influenza A, RSV, and Human Coronavirus NL63 at refrigerated or room temperature up to 48 hours.

Table 1. Percent Reduction in Virus Infectivity After 48 Hours

Samples	Temperature	Percent reduction in virus infectivity relative to 0h		
		Influenza A	RSV	hCoV
Lot 1	4°C	21.97 ± 3.64	59.26 ± 5.90	-23.55 ± 7.85
Lot 2	4°C	9.52 ± 6.79	55.24 ± 3.13	1.50 ± 5.21
Lot 3	4°C	7.06 ± 1.14	65.27 ± 4.02	-18.26 ± 3.99
Lot 1	22°C	-9.89 ± 5.86	76.18 ± 3.50	4.84 ± 3.25
Lot 2	22°C	6.13 ± 2.04	75.85 ± 2.85	21.06 ± 1.55
Lot 3	22°C	11.70 ± 3.15	70.16 ± 1.22	-1.92 ± 3.86

In support of the viral recovery study, the cytotoxicity profile of virus transport media was assessed as well. The results demonstrate that the medium is non-toxic to mammalian host cells.

VIII. CONCLUSIONS

Based on the indications for use, technological characteristics, safety, and performance testing, the subject device, Avantik VTM, meets the requirements that are considered essential for its intended use and supports a decision of substantial equivalence to a legally marketed device.