August 2, 2024

Hardy Diagnostics
Anna Klavins
Senior R&D and Performance Studies Manager
1430 West McCoy Lane
Santa Maria, California 93455

Re: K233534
Trade/Device Name: Viral Transport Medium
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: June 25, 2024
Received: June 25, 2024

Dear Anna Klavins:

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., 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)*
K233534

Device Name
Viral Transport Medium

Indications for Use *(Describe)*
Hardy Diagnostics' Viral Transport Medium (VTM) is intended for the collection and transport of clinical specimens for the preservation of viral agents including, Influenza A, Influenza B, Adenovirus, and Echovirus from the collection site to the testing laboratory. Hardy Diagnostics' VTM is a culture-based media that is intended to be used in standard laboratory procedures for virus culture and diagnostic 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.

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510(k) Summary

July 31, 2024

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

I. General Information

Applicant Name: Hardy Diagnostics
1430 W. McCoy Lane
Santa Maria, CA 93455
Contact Person: Anna Klavins
Senior Technical Services and R&D Manager
Phone: 800-266-2222 x5752
E-mail: KlavinsA@hardydiagnostics.com

II. Device Information

Device Trade Name: Viral Transport Medium
Common Name: Transport culture medium
Classification Name: Culture Media, Non-Propagating Transport
Regulation Number: 21 CFR 866.2390
Class: Class I
Product Code: JSM

III. Predicate Device

Copan Universal Transport Medium (UTM-RT) System (K042970)

IV. Device Description

Hardy Diagnostics' Viral Transport Medium (VTM) is a non-propagating culture-based transport media used for the collection and transport of specimens suspected of containing viruses including Influenza A, Influenza B, Adenovirus, and Echovirus for downstream laboratory test methods. The VTM includes a screw-cap polypropylene tube with skirted conical bottom containing 3mL of transport medium. VTM tubes can be supplied alone, or in a kit format with a mini-tip flocked swab in a sterile peel-pouch. Hardy Diagnostics' VTM is not claimed to be sterile nor is it intended to be sterilized by the end user. Hardy Diagnostics' VTM vials are single use devices.

The product is supplied in multiple configurations described in more detail in table 1 below: tubes alone, or in a kit format with a swab.

Table 1. List of Configurations: Hardy Diagnostics' VTM

Catalog Number	Description	Quantity
R99	VTM, 16×100mm polypropylene tube, 3mL fill	20 tubes/box
R64BX	VTM, 13×80mm polypropylene tube, 3mL fill	100 tubes/box
TPV50	TransPRO VTM System, single 16×100mm polypropylene tube, 3mL fill with individually wrapped, sterile, mini-tip, flocked swab with 80mm breakpoint.	50 each/box

V. Composition of Hardy Diagnostics' VTM

The VTM consists of Hank's Balanced Salt Solution, fetal bovine serum, sucrose to stabilize viral agents, along with Amphotericin B and Gentamicin Sulfate to inhibit bacterial and fungal contaminants. Hardy Diagnostics' VTM also contains a pH indicator (phenol red) to provide a visual check on the medium's pH. VTM appears translucent and light peach in color.

VI. Intended Use/Indications for Use

Hardy Diagnostics' Viral Transport Medium (VTM) is intended for the collection and transport of clinical specimens for the preservation of viral agents including, Influenza A, Influenza B, Adenovirus, and Echovirus from the collection site to the testing laboratory. Hardy Diagnostics' VTM is a culture-based media that is intended to be used in standard laboratory procedures for virus culture and diagnostic assays that utilize stable recoverable infectious viral particles.

VII. Substantial Equivalence Comparison

The following table demonstrates the substantial equivalence comparison of Hardy Diagnostics' Viral Transport Medium to Copan Universal Transport Medium (UTM-RT) System:

	New Device	Predicate Device
	Hardy Diagnostics' Viral Transport Medium K233534	**Copan Universal Transport Medium (UTM-RT) System K042970**
Device Similarities		
Device Product Code and Classification	JSM, Class 1	JSM, Class 1
Intended Use / Indications for Use	Hardy Diagnostics' Viral Transport Medium (VTM) is intended for the collection and transport of clinical specimens for the preservation of viral agents including, Influenza A, Influenza B, Adenovirus, and Echovirus from the collection site to the testing laboratory. Hardy	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

	New Device	Predicate Device
	Hardy Diagnostics' Viral Transport Medium K233534	**Copan Universal Transport Medium (UTM-RT) System K042970**
Device Similarities		
	Diagnostics' VTM is a culture-based media that is intended to be used in standard laboratory procedures for virus culture and diagnostic assays that utilize stable recoverable infectious viral particles.	be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.
Tube Material	Plastic Screw-Cap Tube	Same
pH	7.3 ± 0.2 at 25ºC	Same
Shelf-life	365 days	Same
Storage Temperature	2-25ºC	Same
Single Use Device	Yes	Same
Device Differences		
Media Formulation	• Hank's Balanced Salts Solution (HBSS) • Fetal Bovine Serum • Sucrose • Amphotericin B • Gentamicin Sulfate • Phenol Red	• Hank's Balanced Salts solution (HBSS) • Bovine Serum Albumin (BSA) • Vancomycin • Amphotericin B • Colistin • L-Glutamic Acid • L-Cysteine • HEPES Buffer • Phenol Red • Gelatin • Sucrose
Supported Strains	• Adenovirus • Echovirus • Influenza A • Influenza B	• 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*

VIII. Shelf-life Stability

The shelf life of Hardy Diagnostics' Viral Transport Medium was determined to be 12 months from the date of manufacture when stored at 2-25°C. Three lots of VTM were assessed qualitatively at each time point for functionality and physical characteristics using real time ageing studies. In the real time stability study, media lots were held at 2-8°C and 20-25°C for 12 months. At each timepoint of testing, performance (virus viability), pH, appearance, and fill volume of the media were examined.

A microbial contamination check was performed to verify the stability of the incorporated antibiotics. 100µL of VTM was inoculated to blood agar and SabDex plates, and incubated at 35°C for a minimum of 48 hours to ensure that no contamination was present. No growth was observed on any of the plates tested.

Overall, all results met the study acceptance criteria and support a shelf-life stability of Hardy Diagnostics' VTM for up to 12 months or 365 days.

IX. Viral Recovery Performance

The performance of Hardy Diagnostics' Viral Transport Medium was evaluated for virus viability across various conditions, including two different incubation temperatures and multiple days. The viral recovery study was conducted by spiking a known virus concentration into pooled negative clinical matrix. The contrived viral samples were then inoculated to a minimum of three lots of Viral Transport Medium and held at 2-8°C and 20-25°C for 0, 24, and 48 hours. Aliquots of each lot were pulled at 0, 24, and 48 hours, serially diluted, and inoculated in triplicate into the susceptible host cell line. Host cells were plated at a suitable density in culture medium in microwell plates prior to testing. Virus induced cytopathic effect (CPE) was observed and the viral titer was determined by calculating the fifty-percent tissue culture infective dose ($TCID_{50}$/mL) using the Reed-Muench method. Results were considered acceptable if the average viral recovery for each time point and storage condition demonstrate any percent changes within ±90% (i.e., 1 log change) from baseline (T=0).
The results are presented in Tables 1 and 2.

Table 1: Viral recovery performance of Viral Transport Medium at 20-25°C

Test Strain	Viral recovery ($TCID_{50}$/mL) at T=0 hrs.	Percent changes in viral recovery from the baseline (T= 0 hr.) (-ve indicates reduction)	
		24 hrs.	48 hrs.
Influenza A	$2.12x10^3$	-92.24*	-59.76
Influenza B	$7.23x10^2$	-23.86	-3.45
Echovirus	$1.40x10^5$	-20.55	-25.23
Adenovirus	$1.92x10^3$	18.11	-7.71

* Considered acceptable because subsequent timepoints, i.e., 48 h time point showed < 90% increase.

Table 2: Viral recovery performance of Viral Transport Medium at 2-8°C

Test Strain	Viral recovery ($TCID_{50}$/mL) at T=0 hrs.	Percent Changes in viral recovery from the baseline (T= 0 hr.) (-ve indicates reduction)	
		24 hrs.	48 hrs.
Influenza A	$1.32x10^3$	-5.98	-58.59
Influenza B	$8.05x10^2$	-36.32	-44.27
Echovirus	$1.27x10^5$	21.91	-3.98
Adenovirus	$1.47x10^3$	-20.19	23.11

X. Conclusion

The shelf-life stability results support the storage of Hardy Diagnostics' Viral Transport Medium at 2-25°C for up to 12 months. Viral recovery study results support the recovery of Influenza A, Influenza B, Adenovirus, and Echovirus when stored at 2-8°C and 20-25°C for up to 48 hours from sample collection. Based on the device's technological characteristics, intended use, and performance, the Hardy Diagnostics' VTM is substantially equivalent to the predicate device (K042970).