March 19, 2024

ARX Sciences, Inc.
Chad Werts
President
160 Lawrence Bell Drive
Suite 120
Amherst, New York 14221

Re: K231843
Trade/Device Name: ARX Viral Transport Media Collection and Transport System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: June 12, 2023
Received: June 22, 2023

Dear Chad Werts:

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)
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)*
K231843

Device Name
ARX Viral Transport Media Collection and Transport System

Indications for Use *(Describe)*
ARX Viral Transport Media Collection & Transport System (ARX-VTM) is intended for the collection and transport of clinical specimens containing viruses from the collection site to the testing laboratory. The ARX-VTM is a culture-based media that is intended to be used in the laboratory to perform viral culture or diagnostic assays for viruses including, Influenza A, Parainfluenza type 3, Coronavirus OC43, Respiratory Syncytial Virus (RSV) A, Herpes Simplex virus 1 & 2, Echovirus, and Cytomegalovirus.

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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ARX Sciences Viral Transport Media Collection and Transport System (ARX-VTM)
510(k) Summary

March 19, 2024

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

Applicant name	ARX Sciences, Inc. 160 Lawrence Bell Drive Suite 120, Amherst, NY 14221 USA
Contact Person	Chad Werts, President, ARX Sciences, Inc.
Telephone	+1-(716) 783-6704
Trade Name	ARX Viral Transport Media Collection and Transport System (ARX-VTM)
Common Name	Transport culture medium
Regulation	21 CFR 866.2390
Class	Class I
Product Code	JSM
Predicate Device	K212856

Device Description:

ARX Viral Transport Media Collection and Transport System (ARX-VTM) is a specialized systems for collecting and transporting viruses at 2-8 ºC or 20-25 ºC. The ARX-VTM is for use in laboratories to aid in the diagnosis of infections, especially when there is a delay between specimen collection and processing for up to 72 hrs. ARX Viral Transport Media Collection & Transport System (ARX-VTM) is intended for the collection and transport of clinical specimens containing viruses from the collection site to the testing laboratory. The ARX-VTM is a culture-based media that is intended to be used in the laboratory to perform viral culture or diagnostic assays for viruses including, Influenza A, Parainfluenza type 3, Coronavirus OC43, Respiratory Syncytial Virus (RSV) A, Herpes Simplex virus 1 & 2, Echovirus, and Cytomegalovirus.

Device Specifications: The ARX-VTM contains a non-propagating media supplied in a polypropylene (PP) tube individually with 1 or 3 mL of transport medium and as a kit. The kit contains a PP tube with 1 or 3 mL of transport medium and a sterile peel pouch containing a nylon flocked swab applicator for collecting specimens. Nylon flocked swabs are available in various score points and configurations to facilitate specimen collection from various anatomical sites.

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Table 1: The ARX-VTM is available in the following specifications:

REF	PRODUCT DESCRIPTION		PACKAGING
	TUBE	SWAB	
AR-071	1 mL of ARX-VTM medium in 13x90 mm screw-cap tube with internal shaped conical bottom.	NA	50 tubes per package 10 x 50 tubes per box
AR-071-N	1 mL of ARX-VTM medium in 13x90 mm screw-cap tube with internal shaped conical bottom	One Nasopharyngeal Test Swab with breaking point	50 kits per package 10 x 50 kits per box
AR-071-O	1 mL of ARX-VTM medium in 13x90 mm screw-cap tube with internal shaped conical bottom.	One Oropharyngeal Test Swab with breaking point	50 kits per package 10 x 50 kits per box
AR-103	3 mL of ARX-VTM medium in 16x110 mm screw-cap tube with internal shaped conical bottom.	NA	50 tubes per package 10 x 50 tubes per box
AR-103-N	3 mL of ARX-VTM medium in 16x110 mm screw-cap tube with internal shaped conical bottom.	One Nasopharyngeal Test Swab with breaking point	50 kits per package 10 x 50 kits per box
AR-103-O	3 mL of ARX-VTM medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One Oropharyngeal Test Swab with breaking point	50 kits per package 10 x 50 kits per box

ARX-VTM composition:

The ARX-VTM contains antimicrobial agents to inhibit overgrowth of bacteria, fungi, and yeasts; Hank's Balanced Salt Solution (HBSS) enriched with proteins and sugars for stabilization; and a buffer system to maintain neutral pH. All raw materials used in the manufacture of ARX Viral Transport Media System are qualified before use. Every batch of ARX Viral Transport Media is tested prior to release for pH, osmolarity, turbidity and absence of bacteria growth.

Indications of Use

The ARX Viral Transport Media Collection & Transport System (ARX-VTM) is intended for the collection and transport of clinical specimens containing viruses from the collection site to the testing laboratory. The ARX-VTM is a culture-based media that is intended to be used in the laboratory to perform viral culture or diagnostic assays for viruses including, Influenza A, Parainfluenza type 3, Coronavirus OC43, Respiratory Syncytial Virus (RSV) A, Herpes Simplex virus 1& 2, Echovirus, and Cytomegalovirus.

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Sterilization

The ARX-VTM kit is not claimed to be sterile nor is it intended to be sterilized by the end user. To decrease the chance of contamination the media uses specific manufacturing steps including sterilization of the PP tubes. The media is filtered using a 0.22 µm sterile fiber membrane and then is aseptically filled into the pre-sterilized tubes. ARX-VTM was then validated by a quality control process which evaluates the absence of growth of bacteria and fungi by spreading a 0.1mL of the filtered media on nutrient agar media plates and incubated at 35°C ± 2°C for 24-48 hours. No growth on any of the plates tested was observed.

Performance Characteristics

The performance characteristics of ARX Viral Transport Media System were determined using culture-based recovery studies for the following viruses: Coronavirus, Cytomegalovirus (CMV), Echovirus Type 30, Herpes Simplex Virus Type 1 (HSV-1), Herpes Simplex Virus Type 2 (HSV-2), Influenza A, Parainfluenza 3, and Respiratory Syncytial Virus (RSV). Dilutions of the virus stock suspensions were prepared in clinical matrix and 100 µL was inoculated onto swabs in triplicate. The swabs were transferred into the transport medium and held at both 2-8°C and room temperature (25-30°C). The dilution used for each target was predetermined by demonstrating ~40 to~50% infection via FFU after 24-48 hours in culture.

At time points following inoculation into VTM (0, 24, 48, and 72), each sample was mixed thoroughly, and an aliquot of the suspension was inoculated into monolayer cells cultured with media in 96-well plates. After 24-48 hours of inoculation, the cells were washed, fixed, and immunostained by fluorescein isothiocyanate (FITC)-labeled antibodies for each target virus. The virus titer was determined by visual enumeration of fluorescent foci units (FFU) of each target virus. Table 2 below exhibits the viral recovery performance of the ARX-VTM at 2-8°C. Table 3 below exhibits the viral recovery performance of the ARX-VTM at 25-30°C. Any change of virus titer that was within one log (+/-90%) from the baseline (time point 0) was considered acceptable.

Table 2: Viral recovery performance of ARX-VTM at 2-8°C

Test Strain	Average Recovery in Foci count/mL ($\times 10^4$ Foci Counts/mL)	Percent Changes in viral recovery from the baseline (T= 0 hr.) at 2-8°C (-ve indicates reduction)		
	0 h	24 h	48 h	72 h
Cytomegalovirus	3.52E+04	-0.34%	-5.65%	-29.91%
Coronavirus OC43	1.93E+04	13.53%	-4.90%	-20.29%
Echovirus Type 30	4.29E+04	2.27%	-0.60%	-13.54%
Herpes Simplex Virus Type 1	3.06E+04	-1.26%	-15.39%	-29.74%

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Herpes Simplex Virus Type 2	3.71E+04	-18.51%	-23.41%	-29.78%
Influenza A H3N2	3.39E+04	36.00%	61.69%	26.89%
Parainfluenza Type 3	3.61E+04	61.16%	9.21%	-36.19%
Respiratory Syncytial Type A	1.12E+04	31.29%	-24.14%	-41.66%

Table 3: Viral recovery performance of ARX-VTM at 25-30°C

Test Strain	**Average Recovery in Foci count/mL (×10^4 Foci Counts/mL)**	**Percent Changes in viral recovery from the baseline (T= 0 hr.) at 25-30°C (-ve indicates reduction)**		
	0 h	**24 h**	**48 h**	**72 h**
Cytomegalovirus	3.52E+04	4.85%	-24.86%	-34.58%
Coronavirus OC43	1.93E+04	12.82%	-6.68%	-27.68%
Echovirus Type 30	4.29E+04	10.16%	-5.16%	-19.81%
Herpes Simplex Virus Type 1	3.06E+04	-3.33%	-12.47%	-36.23%
Herpes Simplex Virus Type 2	3.71E+04	-13.19%	-23.06%	-33.85%
Influenza A H3N2	3.39E+04	32.50%	45.29%	8.63%
Parainfluenza Type 3	3.61E+04	41.75%	-16.68%	-46.93%
Respiratory Syncytial Type A	1.12E+04	98.71%*	61.86%	23.07%

* Considered acceptable because subsequent timepoints, i.e., 48 h and 72 h time points showed < 90% increase.

Shelf Life:

To evaluate Shelf-life, three lots of ARX-VTM samples were tested and visually examined for real-time aging to 20 months. The lots of media were stored at 2-8°C or room temperature (25-30°C). Duplicate samples from each lot were visually inspected for turbidity (the appearance of the product is expected to be clear (i.e., no turbidity, not cloudy, and no precipitation) and maintains a pink color (i.e., no color change from pink to yellow). The media lots were tested

for pH (acceptable range: 7.4 ± 0.4) and osmolarity (acceptable range: 290 ± 30 mOsm/Kg). All results were acceptable and support the claim that the ARX-VTM is stable for up to 20 months.

Substantial Equivalence

In-vitro testing was performed and the results for ARX-VTM was compared to that of the predicate device, iClean Viral Transport System (K212856). The results demonstrated that ARX Viral Transport Media Collection & Transport System possesses the same technological characteristics necessary to fulfill the intended use. Based on the similarities in design, manufacturing, indications for use and fundamental scientific technology, the subject device is comparable to the predicate device and does not introduce any new risks of safety or efficacy. The ARX Viral Transport Media System is substantially equivalent to the predicate device for the primary intended use of microbiological sample collection and transport. Below is a summary of comparison table between the ARX-VTM and the predicate device, K212856:

Table 4: Comparison with the Predicate Device

Device & Predicate Device(s):	**Subject Device: K231483**	**Predicate: K212856**	
Device Trade Name	ARX Viral Transport Media Collection and Transport System (ARX-VTM)	iClean Viral Transport System (VTM-RT Kit)	
Device Product Code and Classification	JSM, Class I	JSM, Class I	
General Device Characteristic Similarities	-	-	

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Intended Use/Indications for Use	The ARX Viral Transport Media Collection & Transport System (ARX-VTM) is intended for the collection and transport of clinical specimens containing viruses from the collection site to the testing laboratory. The ARX-VTM is a culture-based media that is intended to be used in the laboratory to perform viral culture or diagnostic assays for viruses including, Influenza A, Parainfluenza type 3, Coronavirus OC43, Respiratory Syncytial Virus (RSV) A, Herpes Simplex virus 1& 2, Echovirus, and Cytomegalovirus.	iClean Viral Transport System (VTM-RT Kit) is intended for the collection and transport of clinical specimens containing respiratory viruses, Chlamydiae, or *Mycoplasma hominis* 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 or bacteria.	
Storage Temperature	2-8°C and 20-25°C	20-25°C	
Tube Material	Plastic Screw-Cap Tube	Same	
Single Use Device	Yes	Same	
General Device Characteristic Differences	-	-	
Media Formulation	* Fetal Bovine Serum * Gentamicin * Amphotericin B * Hanks Balanced Salt Solution (HBSS)	* Hanks Balanced Salt Solution (HBSS) * Bovine Serum Albumin (BSA) * Gentamicin Sulfate * Amphotericin B * Colistin * L-Glutamic acid * HEPES buffer * Phenol Red	
Shelf Life	20 months	12 months	

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Storage Time	Specimen should be processed within 72 hours	Specimen should be processed within 48 hours	
Supported Strains	* Cytomegalovirus * Echovirus Type 30 * Herpes Simplex Virus Type 1 * Herpes Simplex Virus Type 2 * Influenza A * Parainfluenza 3 * Respiratory Syncytial Virus * Coronavirus	* Adenovirus * Cytomegalovirus * Echovirus Type 30 * Herpes Simplex Virus Type 1 * Herpes Simplex Virus Type 2 * Influenza A * Parainfluenza 3 * Respiratory Syncytial Virus * *Chlamydia pneumoniae* * *Chlamydia trachomatis* * *Mycoplasma hominis*	

Conclusion

The ARX Viral Transport Media Collection & Transport System (ARX-VTM) demonstrated recovery of the following tested viruses (Influenza A, Parainfluenza type 3, Coronavirus OC43, Respiratory Syncytial Virus (RSV) A, Herpes Simplex virus 1& 2, Echovirus, and Cytomegalovirus) with an acceptable culture recovery rate when stored at 2-8°C and 20-25°C for up to 72 hours.

Based on devices technological features, intended use and performances, the ARX Viral Transport Media Collection & Transport System (ARX-VTM) is substantially equivalent to the legally marketed predicate device, iClean Viral Transport System (K212856).