March 3, 2021

Merit Medical Systems, Inc.
Alex Bohorquez
Regulatory Affairs Specialist II
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K201674
Trade/Device Name: Cultura Collection and Transport System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM,LIO
Dated: January 12, 2021
Received: January 13, 2021

Dear Alex Bohorquez:

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)
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201674

Device Name
Merit Cultura™ Collection and Transport System

Indications for Use *(Describe)*
The Merit Cultura™ Collection and Transport System is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic/identification techniques. The Merit Cultura™ Collection and Transport System is a culture-based media that can be used for upper respiratory viral diagnostic assays including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus.

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

Sponsor	Submitter Name: Address: Telephone Number: Contact Person: Date Prepared: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 801-208-4685 Alex Bohorquez 27 July 2020 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	Merit Cultura™ Collection and Transport System Specimen Collection and Transport System Transport Culture Medium Devices Class I JSM, LIO 866.2390 Microbiology
Predicate Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product code: 21 CFR §: Premarket Notification: Manufacturer:	Puritan Universal Transport Medium (UTM-RT) Collection and Transport System Specimen Collection and Transport System Transport Culture Medium Devices Class I JSM, LIO 866.2390 K113249 Puritan Medical Products LLC
Device Description	The Merit Cultura™ Collection and Transport System contains a sterile nylon-flocked collection swab with a plastic shaft, a vial with 3.0mL of Viral Transport Medium (VTM) and a sealable biohazard bag. Prior to use, vials should be stored at 2-8°C and 23-25°C. After collection, the transport tube containing the specimen can be stored for up to 120 hours at 2-8°C and 23-25°C.	
Indications for Use	The Merit Cultura™ Collection and Transport System is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic/identification techniques. The Merit Cultura™ Collection and Transport System is a culture-based media that can be used for upper respiratory viral diagnostic assays including Severe	

Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus.

Comparison to Predicate Device

The subject and predicate devices are based on the following same technological elements:

- Provide a device for the collection of patient specimens
- Provide a transport media to preserve specimen in transit to the testing laboratory

	Subject Device	Predicate Device
Intended Use	The Merit Cultura™ Collection and Transport System is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic/identification techniques. The Merit Cultura™ Collection and Transport System is a culture-based media that can be used for upper respiratory viral diagnostic assays including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus.	Puritan UTM-RT Collection and Transport System is intended for the collection and transport of clinical samples containing viruses, chlamydiae, mycoplasmas or ureaplasmas from the collection site to the testing laboratory. The specimen transported in the Puritan UTM-RT can be used in the laboratory to perform viral, chlamydial, mycoplasmal and ureaplasmal culture.
Device Similarities		
Storage Temp.	2-8°C and 23-25°C	Same
List of Ingredients	Hanks Balanced Salt Solution enriched with proteins and sugars with a neutral pH and pH indicator.	Same
Tube Material	Plastic	Same
Single Use Device	Yes	Same
Sterile Device	Yes	Same
Device Differences		
Storage Time	Specimen should be processed within 120 hours	Specimen should be processed within 48 hours
Shelf Life	12 months	15 months

	Samples Transported to Perform	Assays to detect viruses	Assays to detect viruses, chlamydiae, mycoplasmas, or ureaplasmas
	List of Ingredients	• FBS as protein stabilizer • D-glucose as sugar	• BSA as protein stabilizer • Sucrose as sugar • Gelatin • Glutamic acid • HEPES
	Swab Material	Flocked Nylon Fiber Tip with Breaking Point	• Flocked Nylon Fiber Tip with Breaking Point • Polyester tipped with breaking point

Performance Data

Performance Testing:

Culture-Based Studies

Performance of the Cultura Collection and Transport System was evaluated for virus viability using commercial strains of Influenza A, Influenza B, RSV, and Rhinovirus. 600 µL of organism suspension was used to inoculate the Cultura VTM in quadruplicate and stored for 0, 48 hrs., 72 hrs., and 120 hrs. at 2-8°C and at controlled room temperature (23-25°C). At each timepoint, an aliquot of the Cultura VTM and organism suspension was inoculated into the appropriate host cell line. All the cultures were processed using the standard laboratory culture technique. Organism viability was determined by the Reed-Muench method calculation of $TCID_{50}$.

Merit Cultura™ Collection and Transport System preserved the samples of all the organisms tested for up to 120 hours at both controlled room temperature and refrigerated. The organisms evaluated and the results obtained are given in Table 1 below. The table below represents the titer of virus inoculated at T-0. The word “present” confirms the viability of the virus.

Table 1. Viral recovery results for viruses at T0 and T120 hours at 2-8°C and 23-25°C.

Organism	ATCC#	Host Cell lines	ATCC#	Virus recovered at T-0 ($TCID_{50}$)	T-0 Hour		T-120 Hours	
					2-8°C	23-25°C	2-8°C	23-25°C
RSV	VR-26	Hep-2	CCL-23	$10^{1.5}$	Present	Present	Present	Present
Influenza A Virus	VR-1496-TC	MDCK	CCL-34	10^{1}	Present	Present	Present	Present
Influenza B Virus	VR-284	MDCK	CCL-34	$10^{1.5}$	Present	Present	Present	Present
Rhinovirus	VR-1535	H1- Hela	CRL-1958	$10^{1.5}$	Present	Present	Present	Present

Amplification-Based Studies

Performance of the Cultura Collection and Transport System was

evaluated by Real-Time PCR amplification studies using 12 unique, SARS-CoV-2 positive clinical specimens. Testing has been performed in triplicate to show the suitability of the Cultura VTM for the preservation of nucleic acids (RNA and DNA) for down-stream nucleic acid extraction and molecular testing when VTM and collection samples are stored per the instructions provided.

Nucleic acid was detected using the CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel (catalog No. 2019-nCoVEUA-01). The rRT-PCR enzyme used in the master mix was the Thermofisher TaqPath™ 1-Step RT-qPCR Master Mix (catalog No. A15299). RNA was extracted using the Qiagen QIAcube using the QIAmp Viral RNA Mini Kit (catalog No. 52906) per the manufacturer's instructions. Samples were run on the Applied Biosystems 7500 Fast Dx PCR System with SDS version 1.4 software (catalog No. 4406985). T=0 hours, T=72 hours, T=120 hours, and T=240 hours samples were stored in temperature-controlled environments of 2-8°C and 20-25°C.

Results show 100% concordance of the qualitative result (Ct < 40 is a positive result). Ct values were stable for all samples according to lot number, incubation time, or storage condition. See below for details.

Table 2. Test results (Ct, Δ Ct) for samples at storage times (hours) and temperature of 2-8°C

	Storage Time (T, hours) and Detected Markers (N1, N2)								Δ Ct	
	T_0		T_{72}		T_{120}		T_{216}		T_0 vs. T_{120}	
Sample	N1	N2	N1	N2	N1	N2	N1	N2	N1	N2
A	18.56	18.39	18.83	18.48	18.36	18.33	18.14	18.73	-0.20	-0.06
B	18.45	18.55	18.36	18.98	18.47	18.64	18.86	19.13	0.02	0.09
C	25.22	24.66	24.36	24.85	25.57	25.05	24.74	24.34	0.36	0.39
D	31.20	31.40	31.02	30.98	30.51	31.40	30.64	31.56	-0.69	0.00
E	25.72	24.65	24.95	24.79	25.02	24.57	24.99	25.08	-0.69	-0.09
F	38.01	38.58	38.04	39.19	37.95	38.08	38.91	38.60	-0.06	-0.50
G	37.51	37.21	38.13	37.82	38.54	37.90	37.77	38.64	1.03	0.70
H	33.85	34.45	33.81	34.58	33.75	33.86	33.84	34.29	-0.10	-0.59
I	22.05	22.91	22.74	22.98	23.15	23.52	21.91	21.82	1.11	0.61
J	32.40	31.78	31.09	31.32	31.70	31.16	31.19	31.63	-0.70	-0.61
K	20.00	19.38	20.95	19.87	19.68	20.12	19.88	19.63	-0.32	0.74
L	32.08	32.71	32.12	32.70	32.60	32.15	33.75	32.28	0.52	-0.57

Table 3. Test results (Ct, Δ Ct) for samples at storage times (hours) and temperature of 23-25°C

	Storage Time (T, hours) and Detected Markers (N1, N2)								Δ Ct	
	T_0		T_{72}		T_{120}		T_{216}		T_0 vs. T_{120}	
Sample	N1	N2	N1	N2	N1	N2	N1	N2	N1	N2
A	18.40	18.50	18.57	18.67	17.94	18.84	18.00	18.27	-0.46	0.34
B	18.73	18.59	18.49	18.52	19.10	18.21	18.07	18.41	0.37	-0.38
C	24.80	24.88	24.89	24.58	24.91	25.17	25.10	25.82	0.11	0.29
D	31.29	30.10	30.85	30.21	30.76	30.45	30.81	30.87	-0.53	0.35
E	25.43	25.53	24.34	24.79	24.98	24.84	24.88	25.00	-0.45	-0.69
F	38.03	39.08	38.82	38.06	38.13	38.86	37.92	39.66	0.10	-0.22
G	37.91	38.29	37.81	38.13	38.93	38.33	37.57	38.01	1.02	0.04
H	34.51	33.89	34.41	33.36	33.59	34.82	33.74	33.70	-0.92	0.93
I	21.82	23.18	22.43	22.75	21.88	22.61	22.76	23.00	0.06	-0.57
J	31.71	31.70	31.03	31.36	31.86	31.01	31.61	31.58	0.15	-0.69
K	20.14	19.61	19.95	19.86	19.92	19.34	20.64	19.75	-0.23	-0.28
L	33.04	32.15	32.40	33.10	32.46	32.16	32.28	32.70	-0.58	0.01

	Stability Testing: Stability tests were performed on the Merit Cultura™ Collection and Transport System to verify the ability of the aged products to maintain SARS-CoV-2, Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus samples for standard diagnostic/identification techniques up to the expiry date.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, safety, and performance testing, the subject device Merit Cultura™ Collection and Transport System meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Puritan UTM-RT Collection and Transport System, K113249.