May 19, 2026

Maine Molecular Quality Controls, Inc.
Joan Gordon
President
23 Mill Brook Rd.
Saco, Maine 04072

Re: K260577
Trade/Device Name: FilmArray TF Control Panel M527
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed quality control material for clinical microbiology assays
Regulatory Class: Class II
Product Code: PMN
Dated: February 20, 2026
Received: February 20, 2026

Dear Joan Gordon:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

BRYAN M. GRABIAS -S
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Bryan Grabias, Ph.D.
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures 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)*
K260577

Device Name
FilmArray TF Control Panel M527

Indications for Use *(Describe)*
The FilmArray TF Control Panel M527 is intended for use as an external positive and negative assayed quality control to monitor the performance of the BIOFIRE FILMARRAY Tropical Fever (TF) Panel assay on the BIOFIRE FILMARRAY Systems. The BIOFIRE FILMARRAY TF Panel assay qualitatively detects the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3, and 4), Leptospira spp., Plasmodium spp. (including species differentiation of Plasmodium falciparum and Plasmodium vivax/ovale). The FilmArray TF Positive control is composed of synthetic DNA and RNA in stabilizing solutions, buffers, and preservatives. The FilmArray TF Negative control contains buffers and preservatives. The FilmArray TF Control Panel M527 is designed for and intended to be used solely with the BIOFIRE FILMARRAY TF Panel. This product is not intended to replace manufacturer internal controls provided with this device.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

510(k) Number: K260577

Applicant Information:

Applicant: Maine Molecular Quality Controls, Inc.
Address: 23 Mill Brook Road
Saco, Maine 04072

Contact Person: Joan Gordon, President, MMQCI
Phone: 207-885-1072
Email Address: jgordon@mmqci.com

Preparation Date: February 18, 2026

Device

Device Trade Name:	FilmArray TF® Control Panel M527 (M527)
Device Common Name:	Quality Control Material for Microbiology Assays
Device Type:	Assayed quality control material for clinical microbiology assays
Class:	Class II (Special controls)
Regulation:	21 CFR 866.3920
Product code:	PMN

Predicate Device

K251526; FilmArray GI Control Panel M238

Device Description

The FilmArray TF Control Panel M527, P/N M527, is a quality control panel consisting of 2 single use, ready-to-use, liquid controls, FilmArray TF Positive, P/N M52818, and FilmArray TF Negative, P/N M52918. Each kit of FilmArray TF Control Panel M527 is comprised of 6 tubes of FilmArray TF Positive and 6 tubes of FilmArray TF Negative. FilmArray TF Positive contains synthetic DNA and RNA corresponding to genome segments of all the pathogens detected by the BIOFIRE® FILMARRAY Tropical Fever (TF) Panel suspended in a non-infectious solution of buffers, preservatives and stabilizers. FilmArray TF Negative contains buffer and preservatives with no nucleic acid.

Each liquid control of FilmArray TF Control Panel M527 is processed separately according to the BIOFIRE FILMARRAY TF Panel manufacturer's Instructions for Use for patient samples, EDTA whole blood collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4),

Leptospira spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*), as shown in Table 1.

Table 1. Viruses, Parasites, and Bacteria Detected by the BIOFIRE FILMARRAY TF Panel

Viruses
Chikungunya Virus
Dengue Virus
Parasites
Plasmodium spp.
Plasmodium falciparum
Plasmodium vivax/ovale
Bacteria
Leptospira spp.

Intended Use/Indications for Use

The FilmArray TF Control Panel M527 is intended for use as an external positive and negative assayed quality control to monitor the performance of the BIOFIRE FILMARRAY Tropical Fever (TF) Panel assay on the BIOFIRE FILMARRAY Systems. The BIOFIRE FILMARRAY TF Panel assay qualitatively detects the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3, and 4), *Leptospira* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*). The FilmArray TF Positive control is composed of synthetic DNA and RNA in stabilizing solutions, buffers, and preservatives. The FilmArray TF Negative control contains buffers and preservatives. The FilmArray TF Control Panel M527 is designed for and intended to be used solely with the BIOFIRE FILMARRAY TF Panel. This product is not intended to replace manufacturer internal controls provided with this device.

Comparison With Predicate

	Candidate Device	**Predicate Device (K251526)**
Device Trade Name:	FilmArray TF Control Panel M527	FilmArray GI Control Panel M238
Device Characteristic		

Intended Use/Indications For Use	FilmArray® TF Control Panel M527 is intended for use as an external positive and negative assayed quality control to monitor the performance of the BIOFIRE® FILMARRAY Tropical Fever (TF) Panel assay on the BIOFIRE FILMARRAY Systems. The BIOFIRE FILMARRAY TF Panel assay qualitatively detects the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3, and 4), *Leptospira* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*). The FilmArray TF Positive control is composed of synthetic DNA and RNA in stabilizing solutions, buffers, and preservatives. The FilmArray TF Negative control contains buffers and preservatives. The FilmArray TF Control Panel M527 is designed for and intended to be used solely with the BIOFIRE FILMARRAY TF Panel. This product is not intended to replace manufacturer internal controls provided with this device.	FilmArray GI Control Panel M238 is intended for use as an external positive and negative assayed quality control to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of *Campylobacter* (*C. jejuni/C. coli/C. upsaliensis*), *Clostridium difficile* (toxin A/B), *Plesiomonas shigelloides, Salmonella, Vibrio* (*V. parahaemolyticus/V. vulnificus/ V. cholerae*), (including *Vibrio cholerae), Yersinia enterocolitica,* Enteroaggregative *E. coli* (EAEC), Enteropathogenic *E. coli* (EPEC), Enterotoxigenic *E. coli* (ETEC) lt/st, Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2* (*E. coli* O157), *Shigella*/ Enteroinvasive *E. coli* (EIEC), *Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia,* Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A and Sapovirus (Genogroups I, II, IV, and V) using the BIOFIRE® FILMARRAY Gastrointestinal (GI) Panel and the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid assays on BIOFIRE FILMARRAY systems. The FilmArray GI Control Panel M238 is designed for and intended to be used solely with the BIOFIRE GI Panel and the BIOFIRE GI Panel Mid assays. The FilmArray GI Control M239, and FilmArray GI Control M240 contains synthetic RNA transcripts in stabilizing solution, buffers, and preservatives. This product is not intended to replace manufacturer internal controls provided with these devices.
Physical format	Ready-to-Use Liquid	Same
Directions for Use	Process like patient sample	Same
Composition	Synthetic DNA and RNA transcripts suspended in a non-infectious solution of buffers, preservatives and stabilizers.	Synthetic RNA transcripts suspended in a non-infectious solution of buffers, preservatives and stabilizers.
Assay steps monitored	Reverse transcription, amplification, detection, identification	Same
Test System	BIOFIRE FILMARRAY	Same
Pathogen type contained in the control panel	Tropical Fever-associated	GI-associated
Number of pathogen targets monitored simultaneously in one assay	4	22

Standard/Special Control/Guidance Document Referenced (if applicable):
21 CFR 866.3920 Assayed quality control material for clinical microbiology assays

Summary Performance Data
Three lots each of FilmArray TF Positive, P/N M52818, and FilmArray TF Negative, P/N M52918, were manufactured by MMQCI at MMQCI's facility in Saco, Maine. The lots were manufactured and tested such that routine variables, including lots of key manufacturing components, multiple operators, unique pouch lots, multiple instruments, 3 test sites, and testing over time, were incorporated to challenge manufacture processes and product performance. All testing of the FilmArray TF Control Panel M527 was performed using BIOFIRE FILMARRAY Tropical Fever (TF) Panel on the BIOFIRE FILMARRAY 2.0 (FA 2.0) or BIOFIRE FILMARRAY TORCH (FA Torch) systems. One hundred twenty-eight (128) samples of FilmArray TF Positive and one hundred twenty-seven (127) samples of FilmArray TF Negative were tested at 3 sites, for a total of 255 tests, using 9 unique pouch lots across 3 sites, incorporating 13 operators and multiple instruments, over several months.

Results and Conclusion:
Of the 255 FilmArray TF Control Panel M527 samples tested at 3 testing sites, 3 results were invalid and the remaining 252 valid results were correct for an overall correct result rate of 100%. Test results demonstrate robust performance across 3 testing sites, using multiple pouch lots, instruments and operators, confirming that FilmArray TF Control Panel M527 performs as well as, and is as effective as, the predicate device, FilmArray GI Control Panel M238 (K251526), therefore supporting substantial equivalence to that device.

Summary of Reproducibility Study Results for 6 Control Lots at 3 Sites

Summary of Reproducibility Data for FilmArray TF Control Panel M527									
Site	**Total Tests**	**Invalid**	**Correct Pos Control Results**	**Incorrect Pos Control Results**	**Percent Correct Pos**	**Correct Neg Control Results**	**Incorrect Neg Control Results**	**Percent Correct Neg**	**Total Percent Correct**
1	120	0	60	0	100%	60	0	100%	100%
2	73	1	36	0	100%	36	0	100%	100%
3	62	2	30	0	100%	30	0	100%	100%
Total	255	3	126	0	100%	126	0	100%	100%

Performance data demonstrates that the new device, FilmArray TF Control Panel M527, is as safe and effective as the predicate device, FilmArray GI Control Panel M238 (K251526).