August 14, 2025

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

Re: K251526
Trade/Device Name: FilmArray GI Control Panel M238
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed Quality Control Material For Clinical Microbiology Assays
Regulatory Class: Class II
Product Code: PMN
Dated: May 16, 2025
Received: May 19, 2025

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 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.

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

Digitally signed by Bryan M. Grabias -S
Date: 2025.08.14 09:27:26 -04'00'

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)*

K251526

Device Name

FilmArray® GI Control Panel M238 (M238)

Indications for Use *(Describe)*

The FilmArray GI Control Panel M238 is intended for use as an external positive and negative assayed quality control to monitor performance of the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel and the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid assays on the BIOFIRE FILMARRAY systems. BIOFIRE FILMARRAY Gastrointestinal (GI) Panel and the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid assays qualitatively detect the following targets: *Campylobacter (C. jejuni/C. coli/C. upsaliensis), Clostridium (Clostridioides) difficile toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio (V. parahaemolyticus/V. vulnificus/V. 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. The FilmArray GI Control Panel M238 contains synthetic RNA transcripts in stabilizing solution, buffers, and preservatives. The FilmArray GI Control Panel M238 is designed for and intended to be used solely with the BIOFIRE FILMARRAY GI Panel and the BIOFIRE FILMARRAY GI Panel Mid assays. This product is not intended to replace manufacturer internal controls provided with these devices.

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: K251526

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: August 1, 2025

Device

Device Trade Name:	FilmArray® GI Control Panel M238 (M238)
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

K202196; BioFire® RP2.1/RP2.1*plus* Control Panel

Device Description

FilmArray GI Control Panel M238, P/N M238, is a quality control panel consisting of 2 single use, ready-to-use, liquid controls, FilmArray GI Control M239, P/N M239, and FilmArray GI Control M240, P/N M240. Each kit of FilmArray GI Control Panel M238 is comprised of 6 tubes of M239 and 6 tubes of M240. Together the 2 controls contain synthetic RNA corresponding to genome segments of all the pathogens detected by the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel and BIOFIRE FILMARRAY GI Panel Mid assays, suspended in a non-infectious solution of buffers, preservatives and stabilizers.

Each liquid control of FilmArray GI Control Panel M238 is processed separately according to the BIOFIRE GI Panel and BIOFIRE GI Panel Mid manufacturer's Instructions for Use for patient

samples, stool samples in Cary Blair transport media obtained from individuals with signs and/or symptoms of gastrointestinal infection.

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

Bacteria	Viruses
Campylobacter (C. jejuni/C. coli/ C. upsaliensis)	Adenovirus F 40/41
Clostridium difficile (toxin A/B)	Astrovirus
Plesiomonas shigelloides	Norovirus GI/GII
Salmonella	Rotavirus A
Vibrio (V. parahaemolyticus/V. vulnificus/ V. cholerae)	Sapovirus (Genogroups I, II, IV, and V)
V. cholerae	
Yersinia enterocolitica	
Diarrheagenic *E. coli/Shigella*	Parasites
Enteroaggregative *E. coli* (EAEC)	*Cryptosporidium*
Enteropathogenic *E. coli* (EPEC)	*Cyclospora cayetanensis*
Enterotoxigenic *E. coli* (ETEC) lt/st	*Entamoeba histolytica*
Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*	*Giardia lamblia*
E. coli O157	
Shigella/Enteroinvasive *E. coli* (EIEC)	

Table 2. **Bacteria, Viruses, and Parasites Detected by the BIOFIRE FILMARRAY GI Panel Mid**

Bacteria	Viruses
Campylobacter (C. jejuni/C. coli/ C. upsaliensis)	Norovirus GI/GII
Clostridioides (Clostridium) difficile (toxin A/B)	
Salmonella	
Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*	Parasites
Shigella/Enteroinvasive *E. coli* (EIEC)	*Cryptosporidium*
Vibrio (V. parahaemolyticus/V. vulnificus/ V. cholerae)	*Cyclospora cayetanensis*
Yersinia enterocolitica	*Giardia lamblia*

Intended Use/Indications for Use

The FilmArray GI Control Panel M238 is intended for use as an external positive and negative assayed quality control to monitor performance of the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel and the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid assays on the BIOFIRE FILMARRAY systems. BIOFIRE FILMARRAY Gastrointestinal (GI) Panel and the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid assays qualitatively detect the following targets: *Campylobacter* (*C. jejuni*/*C. coli*/*C. upsaliensis*), *Clostridium* (*Clostridioides*) *difficile* toxin A/B, *Plesiomonas shigelloides*, *Salmonella*, *Vibrio (V. parahaemolyticus/V. vulnificus/V. 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. The FilmArray GI Control Panel M238 contains synthetic RNA transcripts in stabilizing solution, buffers, and preservatives. The FilmArray GI Control Panel M238 is designed for and intended to be used solely with the BIOFIRE FILMARRAY GI Panel and the BIOFIRE FILMARRAY GI Panel Mid assays. This product is not intended to replace manufacturer internal controls provided with these devices.

Comparison With Predicate

Device & Predicate Device(s):	K251526 (Candidate)	K202196 (Predicate)
Device Trade Name	FilmArray GI Control Panel M238	BioFire RP2.1/RP2.1*plus* Control Panel M441
General Device Characteristic Similarities		
Intended Use/Indications For Use	The FilmArray GI Control Panel M238 is intended for use as an external positive and negative assayed quality control to monitor performance of the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel and the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid assays on the BIOFIRE FILMARRAY systems. BIOFIRE FILMARRAY Gastrointestinal (GI) Panel and the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid assays qualitatively detect the following targets: *Campylobacter* (*C. jejuni*/*C. coli*/*C. upsaliensis*), *Clostridium*	BioFire RP2.1/RP2.1plus Control Panel M441 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 Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/ Enterovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H1-2009, Influenza A subtype H3, Influenza B, Middle East Respiratory Syndrome Coronavirus, Parainfluenza Virus, Respiratory Syncytial

Device & Predicate Device(s):	K251526 (Candidate)	K202196 (Predicate)
	(*Clostridioides*) *difficile* toxin A/B, *Plesiomonas shigelloides*, *Salmonella*, *Vibrio (V. parahaemolyticus/V. vulnificus/V. 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. The FilmArray GI Control Panel M238 contains synthetic RNA transcripts in stabilizing solution, buffers, and preservatives. The FilmArray GI Control Panel M238 is designed for and intended to be used solely with the BIOFIRE FILMARRAY GI Panel and the BIOFIRE FILMARRAY GI Panel Mid assays. This product is not intended to replace manufacturer internal controls	Virus, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae,* and *Mycoplasma pneumoniae* on the BIOFIRE Respiratory Panel 2.1 (RP2.1), BIOFIRE Respiratory Panel 2.1 plus (RP2.1plus) and BIOFIRE Respiratory Panel 2.1-EZ (RP2.1-EZ) assay performed on the BIOFIRE FILMARRAY systems. BIOFIRE RP2.1/RP2.1plus Positive control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the BIOFIRE RP2.1, BIOFIRE RP2.1plus and BIOFIRE RP2.1-EZ assay. This product is not intended to replace manufacturer controls provided with the device.

Device & Predicate Device(s):	K251526 (Candidate)	K202196 (Predicate)
	provided with these devices.	
Physical format	Ready-to-Use Liquid	Same
Directions for Use	Process like patient sample	Same
Composition	Synthetic RNA transcripts suspended in a non-infectious solution of buffers, preservatives and stabilizers.	Same
Assay steps monitored	Reverse transcription, amplification, detection, identification	Same
Test System	BIOFIRE FILMARRAY 2.0 and BIOFIRE FILMARRAY Torch	Same
General Device Characteristic Differences		
Targets	*Campylobacter* (*C. jejuni*/*C. coli*/*C. upsaliensis*), *Clostridium* (*Clostridioides*) *difficile* toxin A/B, *Plesiomonas shigelloides*, *Salmonella*, *Vibrio (V. parahaemolyticus/V. vulnificus/V. 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	Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/ Enterovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H1-2009, Influenza A subtype H3, Influenza B, Middle East Respiratory Syndrome Coronavirus, Parainfluenza Virus, Respiratory Syncytial Virus, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*

Device & Predicate Device(s):	K251526 (Candidate)	K202196 (Predicate)
	GI/GII, Rotavirus A, and Sapovirus	
Number of pathogen targets monitored simultaneously in one assay	22	23

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

Summary Performance Data
Six lots each of FilmArray GI Control M239 and FilmArray GI Control M240 were manufactured by MMQCI at MMQCI's facility in Saco, Maine. All testing of the FilmArray GI Control Panel M238 was performed using BIOFIRE FILMARRAY Gastrointestinal (GI) Panel assay on the BIOFIRE FILMARRAY 2.0 or BIOFIRE FILMARRAY Torch Systems. Seventy-nine (79) samples of FilmArray GI Control M239 and eighty-six (86) samples of FilmArray GI Control M240 were tested at 2 sites, for a total of 165 tests, using 20 unique BIOFIRE FIMARRAY GI Panel reagent lots, incorporating 9 operators and multiple instruments, over several months.

Results and Conclusions:
Of the 165 samples tested, all 165 results were valid and 100% correct**.** Test results demonstrate robust performance across 2 testing sites, using multiple test reagent lots, instruments and operators, confirming that FilmArray GI Control Panel M238 performs as well as, and is as effective and safe as, the predicate device, BIOFIRE RP2.1/RP2.1*plus* Control Panel M441 (K202196), therefore supporting substantial equivalence to that device.

Summary of Reproducibility Study Results for 6 Control Lots at 2 Sites

Summary of Performance Data for FilmArray GI Control Panel M238									
Site	Total Tests	Invalid	Correct M239 Control Results	Incorrect M239 Control Results	Percent Correct M239 Control	Correct M240 Control Results	Incorrect M240 Control Results	Percent Correct M240 Control	Total Percent Correct
1	40	0	20	0	100%	20	0	100%	100%
2	125	0	59	0	100%	66	0	100%	100%
Total	165	0	79	0	100%	86	0	100%	100%

FilmArray GI Control Panel M238 performance is substantially equivalent to predicate device, BioFire RP2.1/RP2.1*plus* Control Panel M441 (K202196).