October 21, 2026

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

Re: K262573
Trade/Device Name: SPOTFIRE VG Control Panel M534, SPOTFIRE VG Negative Control
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed quality control material for clinical microbiology assays
Regulatory Class: Class II
Product Code: PMN
Dated: July 24, 2026
Received: July 27, 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

HIMANI BISHT -S

Himani Bisht, Ph.D.
Assistant Director
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)*
K262573

Device Name
SPOTFIRE VG Control Panel M534
SPOTFIRE VG Negative Control

Indications for Use *(Describe)*

SPOTFIRE® VG Control Panel M534 Indications for Use:
The SPOTFIRE® VG Control Panel M534 is intended for use as an external positive and negative assayed quality control to monitor the performance of the BIOFIRE® SPOTFIRE Vaginitis (VG) Panel (SPOTFIRE VG Panel) on BIOFIRE SPOTFIRE System. The SPOTFIRE VG Panel assay qualitatively detects the following target pathogens: Bacterial Vaginosis (BV) [Fannyhessea (Atopobium) vaginae, Bacterial Vaginosis-Associated Bacterium 2 (BVAB2), Lactobacillus crispatus, Lactobacillus gasseri/paragasseri, Lactobacillus jensenii/mulieris, and Sneathia vaginalis (amnii)/sanguinegens], Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Candida dubliniensis, and Trichomonas vaginalis. The SPOTFIRE VG Positive Control is composed of synthetic DNA in stabilizing solutions, buffers, and preservatives. The SPOTFIRE VG Negative Control contains buffers and preservatives. The SPOTFIRE VG Control Panel M534 is designed for and intended to be used solely with the SPOTFIRE VG Panel. This product is not intended to replace manufacturer internal controls provided with this device.

SPOTFIRE® VG Negative Control Indications for Use:
The SPOTFIRE® VG Negative Control is intended for use as an external negative assayed quality control to monitor the performance of the BIOFIRE® SPOTFIRE Vaginitis (VG) Panel on BIOFIRE SPOTFIRE System. The SPOTFIRE VG Panel assay qualitatively detects the following target pathogens: Bacterial Vaginosis (BV) [Fannyhessea (Atopobium) vaginae, Bacterial Vaginosis-Associated Bacterium 2 (BVAB2), Lactobacillus crispatus, Lactobacillus gasseri/paragasseri, Lactobacillus jensenii/mulieris, and Sneathia vaginalis (amnii)/sanguinegens], Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Candida dubliniensis, and Trichomonas vaginalis. The SPOTFIRE VG Negative Control contains buffers and preservatives. The SPOTFIRE VG Negative Control is designed for and intended to be used solely with the SPOTFIRE VG 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: K262573

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: July 24, 2026

Device

Device Trade Name:	SPOTFIRE VG Control Panel M534 SPOTFIRE VG Negative Control
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

K241289; SPOTFIRE RSP Pos & Neg Controls

Device Description

The SPOTFIRE® VG Control Panel M534, P/N M534, is a quality control panel consisting of 2 single use, ready-to-use, liquid controls, SPOTFIRE VG Positive Control, P/N M53521, and SPOTFIRE VG Negative Control, P/N M53621. Each kit of SPOTFIRE VG Control Panel M534 is comprised of 6 tubes of SPOTFIRE VG Positive Control and 6 tubes of SPOTFIRE VG Negative Control. SPOTFIRE VG Negative Control (6) is also available in a separate kit box to allow the end user to check for environmental contamination by testing additional negative controls. SPOTFIRE VG Positive Control contains synthetic DNA corresponding to genome segments of all the pathogens detected by the BIOFIRE® SPOTFIRE Vaginitis (VG) Panel (SPOTFIRE VG

Panel) suspended in a non-infectious solution of buffers, preservatives and stabilizers. SPOTFIRE VG Negative Control contains buffer and preservatives with no nucleic acid.

Each liquid control of SPOTFIRE VG Control Panel M534 is processed like a patient sample while following the SPOTFIRE VG Panel manufacturer's Instructions for Use to identify the control samples as 'QC'. The following analytes are identified and differentiated using the SPOTFIRE VG Panel: Bacterial Vaginosis (BV), [Analytes not reported: *Fannyhessea (Atopobium) vaginae, Bacterial Vaginosis-Associated Bacterium 2* (BVAB2), *Lactobacillus crispatus, Lactobacillus gasseri/paragasseri, Lactobacillus jensenii/mulieris,* and *Sneathia vaginalis (amnii)/sanguinegens*], *Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Candida dubliniensis*, and *Trichomonas vaginalis*, as shown in Table 1.

Table 1. Analytes Detected by the SPOTFIRE VG Control Panel

Bacteria
Bacterial Vaginosis (BV)
Parasites
Trichomonas vaginalis
Yeast
Candida albicans
Candida dubliniensis
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis

Intended Use/Indications for Use

SPOTFIRE® VG Control Panel M534:

The SPOTFIRE® VG Control Panel M534 is intended for use as an external positive and negative assayed quality control to monitor the performance of the BIOFIRE® SPOTFIRE Vaginitis (VG) Panel (SPOTFIRE VG Panel) on BIOFIRE SPOTFIRE System. The SPOTFIRE VG Panel assay qualitatively detects the following target pathogens: Bacterial Vaginosis (BV) [*Fannyhessea (Atopobium) vaginae, Bacterial Vaginosis-Associated Bacterium 2* (BVAB2), *Lactobacillus crispatus, Lactobacillus gasseri/paragasseri, Lactobacillus jensenii/mulieris, and Sneathia vaginalis (amnii)/sanguinegens*], *Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Candida dubliniensis,* and *Trichomonas vaginalis*. The SPOTFIRE VG Positive Control is composed of synthetic DNA in stabilizing solutions, buffers, and preservatives. The SPOTFIRE VG Negative Control contains buffers and preservatives. The

SPOTFIRE VG Control Panel M534 is designed for and intended to be used solely with the SPOTFIRE VG Panel. This product is not intended to replace manufacturer internal controls provided with this device.

SPOTFIRE® VG Negative Control:

The SPOTFIRE® VG Negative Control is intended for use as an external negative assayed quality control to monitor the performance of the BIOFIRE® SPOTFIRE Vaginitis (VG) Panel (SPOTFIRE VG Panel) on BIOFIRE SPOTFIRE System. The SPOTFIRE VG Panel assay qualitatively detects the following target pathogens: Bacterial Vaginosis (BV) [*Fannyhessea* (*Atopobium) vaginae, Bacterial Vaginosis-Associated Bacterium* 2 (BVAB2), *Lactobacillus crispatus*, *Lactobacillus gasseri/paragasseri, Lactobacillus jensenii/mulieris,* and *Sneathia vaginalis (amnii)/sanguinegens*], *Candida albicans*, *Candida glabrata, Candida krusei*, *Candida parapsilosis*, *Candida tropicalis, Candida dubliniensis*, and *Trichomonas vaginalis.* The SPOTFIRE VG Negative Control contains buffers and preservatives. The SPOTFIRE VG Negative Control is designed for and intended to be used solely with the SPOTFIRE VG Panel.

Comparison With Predicate

	Candidate Device	**Predicate Device (K241289)**
Device Trade Name:	SPOTFIRE VG Control Panel M534 SPOTFIRE VG Negative Control	SPOTFIRE RSP Pos & Neg Controls SPOTFIRE RSP Negative Control
Device Characteristic		
Intended Use/Indications For Use	The SPOTFIRE® VG Control Panel M534 is intended for use as an external positive and negative assayed quality control to monitor the performance of the BIOFIRE® SPOTFIRE Vaginitis (VG) Panel (SPOTFIRE VG Panel) on BIOFIRE SPOTFIRE System. The SPOTFIRE VG Panel assay qualitatively detects the following target pathogens: Bacterial Vaginosis (BV) [*Fannyhessea (Atopobium) vaginae, Bacterial Vaginosis-Associated Bacterium 2* (BVAB2), *Lactobacillus crispatus, Lactobacillus gasseri/paragasseri, Lactobacillus jensenii/mulieris, and Sneathia vaginalis (amnii)/sanguinegens*], *Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Candida dubliniensis,* and *Trichomonas vaginalis*. The SPOTFIRE VG Positive Control is composed of synthetic DNA in stabilizing solutions, buffers, and preservatives. The SPOTFIRE VG Negative Control contains buffers and preservatives. The SPOTFIRE VG Control Panel M534 is designed for and intended to	The SPOTFIRE® RSP Pos & Neg Controls kit is intended for use (as applicable) as an external positive and negative assayed quality control to monitor performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of *Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae, Streptococcus dysgalactiae* (Group C/G Strep), *Streptococcus pyogenes* (Group A Strep), Adenovirus, Coronavirus SARS-CoV-2, Coronavirus (seasonal), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A Subtype H1-2009, Influenza A Subtype H3, Influenza B, Parainfluenza Virus and Respiratory Syncytial Virus using the BIOFIRE® SPOTFIRE Respiratory (R) Panel, BIOFIRE SPOTFIRE Respiratory (R) Panel Mini, BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel and BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel Mini on the BIOFIRE SPOTFIRE System. SPOTFIRE

	be used solely with the SPOTFIRE VG Panel. This product is not intended to replace manufacturer internal controls provided with this device. The SPOTFIRE® VG Negative Control is intended for use as an external negative assayed quality control to monitor the performance of the BIOFIRE® SPOTFIRE Vaginitis (VG) Panel (SPOTFIRE VG Panel) on BIOFIRE SPOTFIRE System. The SPOTFIRE VG Panel assay qualitatively detects the following target pathogens: Bacterial Vaginosis (BV) [*Fannyhessea* (*Atopobium) vaginae, Bacterial Vaginosis-Associated Bacterium* 2 (BVAB2), *Lactobacillus crispatus*, *Lactobacillus gasseri/paragasseri, Lactobacillus jensenii/mulieris,* and *Sneathia vaginalis (amnii)/sanguinegens*], *Candida albicans*, *Candida glabrata, Candida krusei*, *Candida parapsilosis*, *Candida tropicalis, Candida dubliniensis*, and *Trichomonas vaginalis.* The SPOTFIRE VG Negative Control contains buffers and preservatives. The SPOTFIRE VG Negative Control is designed for and intended to be used solely with the SPOTFIRE VG Panel. This product is not intended to replace manufacturer internal controls provided with this device.	RSP Pos & Neg Controls is designed for and intended to be used solely with the BIOFIRE SPOTFIRE R Panel, BIOFIRE SPOTFIRE R Panel Mini, BIOFIRE SPOTFIRE R/ST Panel, and BIOFIRE SPOTFIRE R/ST Panel Mini assays. The SPOTFIRE RSP Positive Control contains synthetic RNA transcripts in stabilizing solution, and the SPOTFIRE RSP Negative Control contains buffers and preservatives. This product is not intended to replace manufacturer internal controls provided with these devices. Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements SPOTFIRE® RSP Negative Control is intended for use (as applicable) as an external negative assayed quality control to monitor performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of *Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae, Streptococcus dysgalactiae* (Group C/G Strep), *Streptococcus pyogenes* (Group A Strep), Adenovirus, Coronavirus SARS-CoV-2, Coronavirus (seasonal), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A Subtype H1-2009, Influenza A Subtype H3, Influenza B, Parainfluenza Virus and Respiratory Syncytial Virus using the BIOFIRE® SPOTFIRE Respiratory (R) Panel, BIOFIRE SPOTFIRE Respiratory (R) Panel Mini, BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel, and BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel Mini on the BIOFIRE SPOTFIRE System. SPOTFIRE RSP Negative Control is designed for and intended to be used solely with the BIOFIRE SPOTFIRE R Panel, BIOFIRE SPOTFIRE R Panel Mini, BIOFIRE SPOTFIRE R/ST Panel, and BIOFIRE SPOTFIRE R/ST Panel Mini assays. SPOTFIRE RSP Negative Control is comprised of a solution of buffer and preservatives that does not contain target analytes. This product is not intended to replace manufacturer internal controls provided with these devices. Quality control materials should be used in accordance with local, state, federal regulations, and accreditation

		requirements.
Physical format	Ready-to-Use Liquid	Same
Directions for Use	Process like a patient sample following the Instructions for Use to identify the controls as QC.	Same
Composition	Synthetic DNA 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	Amplification, detection, identification	Reverse transcriptase, amplification, detection, identification
Test System	BIOFIRE SPOTFIRE	Same
Pathogen type contained in the control panel	Vaginitis-associated	Respiratory-associated
Number of pathogen targets monitored simultaneously in one assay	Multiple	Same

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 of SPOTFIRE VG Positive Control, P/N M53521, and SPOTFIRE VG Negative Control, P/N M53621, 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, 8 test sites, and testing over time, were incorporated to challenge manufacture processes and product performance. All testing of the SPOTFIRE VG controls was performed using BIOFIRE SPOTFIRE Vaginitis (VG) Panel (SPOTFIRE VG Panel) on the BIOFIRE SPOTFIRE System. One hundred eighty-eight (188) samples of SPOTFIRE VG Positive Control and one hundred eighty-eight (188) samples of SPOTFIRE VG Negative Control samples were tested at 8 sites, for a total of 376 tests, using 19 unique pouch lots across 8 sites, incorporating multiple operators and instruments, over several months.

Results and Conclusion:

Of the 376 SPOTFIRE VG control samples tested at 8 testing sites, 372 results were valid with 369 correct calls for an overall correct result rate of 99.2%. Test results demonstrate robust performance across 8 testing sites, using multiple pouch lots, instruments and operators, confirming that SPOTFIRE VG controls perform as well as, and is as effective as, the predicate device, SPOTFIRE RSP Pos & Neg Controls (K241289), therefore supporting substantial equivalence to that device.

Summary of Reproducibility Study Results for 6 Control Lots at 8 Sites

Summary of Reproducibility Data for SPOTFIRE VG Positive and Negative Controls									
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	85	0	43	0	100%	40	2	95.2%	97.6%
2	47	0	24	0	100%	23	0	100%	100%
3	20	0	7	0	100%	13	0	100%	100%
4	4	0	2	0	100%	2	0	100%	100%
5	47	0	24	0	100%	23	0	100%	100%
6	6	0	3	0	100%	3	0	100%	100%
7	42	0	21	0	100%	21	0	100%	100%
8	125	4	60	0	100%	60	1	98.4%	99.2%
Total	376	4	184	0	100%	185	3	98.4%	99.2%

*Invalid results were not included in percent correct

Conclusion:

Performance data demonstrates that the new devices, SPOTFIRE VG Control Panel M534 and SPOTFIRE VG Negative Control, are as safe and effective as the predicate device, SPOTFIRE RSP Pos & Neg Controls (K241289).