May 30, 2024

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

Re: K241289
Trade/Device Name: SPOTFIRE RSP Pos & Neg Controls; SPOTFIRE RSP 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: May 6, 2024
Received: May 7, 2024

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.

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,

Joseph Briggs -S

Joseph Briggs, Ph.D.
Deputy Branch Chief
Viral Respiratory and HPV 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)*
K241289

Device Name
SPOTFIRE® RSP Pos & Neg Controls
SPOTFIRE® RSP Negative Control

Indications for Use *(Describe)*
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 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.

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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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SECTION 4: Special 510(k) Summary

510(k) Number:

Purpose for submission: Changes to existing device (reference K233611) are the addition of BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini to the intended use of SPOTFIRE RSP Pos & Neg Controls, and the packaging of 6 SPOTFIRE® RSP Positive Controls and 6 SPOTFIRE® RSP Negative Controls together in a single kit box. No other changes have been made to device K233611, SPOTFIRE RSP Pos & Neg Controls.

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 extension 201
Fax: 207-885-1079
Email Address: jgordon@mmqci.com

Preparation Date: April 28, 2024

Device

Device Trade Name: SPOTFIRE® RSP Pos & Neg Controls
SPOTFIRE® RSP Negative Control
Device Type: Assayed quality control material for clinical microbiology assays
Class: Class II (Special controls)
Product code: PMN

Predicate Device

K233611: SPOTFIRE® RSP Pos & Neg Controls
SPOTFIRE® RSP Positive Control
SPOTFIRE® RSP Negative Control

Proposed Change:

Purpose for submission: Changes to existing device (reference K233611) are the addition of the BIOFIRE® SPOTFIRE® R/ST Panel Mini to the intended use of SPOTFIRE RSP Pos & Neg Controls, and the packaging of 6 SPOTFIRE® RSP Positive Controls and 6 SPOTFIRE® RSP Negative Controls together in a single kit box, with subsequent updates of the Indications of Use (FDA Form 3881), and Package Inserts for SPOTFIRE RSP Pos & Neg Controls and SPOTFIRE RSP Negative Control. SPOTFIRE RSP Negative Control (6) will continue to be packaged in a single kit, as for K233611. No other changes have been made to device K233611, SPOTFIRE RSP Pos & Neg Controls.

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Description of Modified Device (inclusion of SPOTFIRE R/ST Panel Mini and packaging change):

SPOTFIRE RSP Pos & Neg Controls, P/N M425, is a quality control panel consisting of 12 ready-to-use, liquid controls, 6 of SPOTFIRE RSP Positive Control (Positive Control), P/N M42638, and 6 of SPOTFIRE RSP Negative Control (Negative Control), P/N M42738, in a single kit box, and a separate kit of 6 additional SPOTFIRE RSP Negative Controls (Negative Control), P/N M42738. The separate kit of SPOTFIRE RSP Negative Control allows and encourages the end user to check for environmental contamination by testing additional negative controls. The Positive Control contains non-infectious surrogate control material; a solution of synthetic RNA transcripts in buffer, stabilizers and preservatives. The RNA in the Positive Control carries RNA segments of all the respiratory and sore throat pathogens detected by 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 assays, performed on the BIOFIRE SPOTFIRE System. (see **Tables 1-4** below) SPOTFIRE RSP Pos & Neg Controls are specifically 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 on the BIOFIRE SPOTFIRE System. The Negative Control contains buffer and preservatives with no RNA. Each liquid control of SPOTFIRE RSP Pos & Neg Controls is processed separately according to the SPOTFIRE Panel assay manufacturer's Instructions for Use for patient samples (nasopharyngeal swabs or throat swabs placed in transport media) obtained from individuals with signs and symptoms of respiratory tract infection or pharyngitis. Engineering drawings, schematics, etc. are not applicable to the device (device is a reagent).

Table 1. Respiratory pathogens detected by BIOFIRE SPOTFIRE R Panel

Viruses	**Bacteria**
Adenovirus	*Chlamydia pneumoniae*
Coronavirus SARS-CoV-2	*Mycoplasma pneumoniae*
Coronavirus (seasonal)	*Bordetella parapertussis*
Human Metapneumovirus	*Bordetella pertussis*
Human Rhinovirus/Enterovirus	
Influenza A Virus	
Influenza A virus A/H1-2009	
Influenza A virus A/H3	
Influenza B Virus	
Parainfluenza	
Respiratory Syncytial Virus	

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Table 2. Respiratory viruses detected by the BIOFIRE SPOTFIRE R Panel Mini
Coronavirus SARS-CoV-2
Human Rhinovirus
Influenza A Virus
Influenza B Virus
Respiratory Syncytial Virus

Table 3. Respiratory and sore throat pathogens detected by BIOFIRE SPOTFIRE R/ST Panel	
Viruses (Respiratory and Sore Throat)	**Bacteria (Respiratory and Sore Throat)**
Adenovirus	*Chlamydia pneumoniae*
Coronavirus SARS-CoV-2	*Mycoplasma pneumoniae*
Coronavirus (seasonal)	**Bacteria (Respiratory Only)**
Human Metapneumovirus	*Bordetella parapertussis*
Human Rhinovirus/Enterovirus	*Bordetella pertussis*
Influenza A Virus	**Bacteria (Sore Throat Only)**
Influenza A virus A/H1-2009	*Streptococcus dysgalactiae* (group C/G Strep)
Influenza A virus A/H3	*Streptococcus pyogenes* (group A Strep)
Influenza B Virus	
Parainfluenza	
Respiratory Syncytial Virus	

Table 4. Respiratory and sore throat pathogens detected by the BIOFIRE SPOTFIRE R/ST Panel Mini.
Streptococcus pyogenes (group A Strep)
Coronavirus SARS-CoV-2
Human Rhinovirus
Influenza A Virus
Influenza B Virus
Respiratory Syncytial Virus

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Modified Device Intended Use of SPOTFIRE RSP Pos & Neg Controls to include the addition SPOTFIRE Respiratory R/ST Panel Mini

SPOTFIRE RSP Pos & Neg Controls:

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 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:

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.

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Substantial Equivalence

Maine Molecular Quality Controls, Inc. (MMQCI) proposes that changes made to the labeling and packaging for SPOTFIRE RSP Pos & Neg Controls do not impact substantial equivalence to the predicate device (K233611), SPOTFIRE® RSP Pos & Neg Controls. The manufacturing processes and components used to manufacture SPOTFIRE RSP Pos & Neg Controls are the same as those of the predicate device. No changes have been made to the predicate device, other than labeling and kit box. In addition, the targets detected by the SPOTFIRE R/ST Panel Mini are included in the SPOTFIRE R/ST Panel.

Table 5. Substantial Equivalence of Predicate Device **Characteristic**	**Modified Device: SPOTFIRE RSP Pos & Neg Controls**	**Predicate Device: K233611 SPOTFIRE RSP Pos & Neg Controls**
Intended Use	External assayed quality control to monitor *in vitro* lab nucleic acid testing using SPOTFIRE R Panel, SPOTFIRE R Panel Mini, SPOTFIRE R/ST Panel, and SPOTFIRE R/ST Panel Mini performed on SPOTFIRE System.	Same except the Predicate Intended Use did not include the SPOTFIRE R/ST Panel Mini.
Labeling	SPOTFIRE R/ST Panel Mini is included in the Product Insert with no changes to kit or tube labels.	SPOTFIRE R/ST Panel Mini is not included in the Product Insert.
Physical format	Ready-to-Use Liquid	Same
Packaging	1 kit box for 6 each Positive and Negative Controls, and 1 kit box for 6 Negative Controls.	1 kit box for 6 Positive Controls, and 1 kit box for 6 Negative Controls.
Directions for Use	Process like patient sample.	Same
Composition	Synthetic RNA transcripts	Same
Assay steps monitored	Reverse transcription, amplification, detection, identification	Same
Test System	SPOTFIRE	same
Number of targets monitored in one assay	Multiple	Same targets. Predicate did not include a report for the 5 SPOTFIRE R/ST Panel Mini pathogens alone. However, all 5 pathogens are detected using the SPOTFIRE R/ST Panel, K233611.
Pathogens contained in the control panel	Respiratory and Sore Throat	same

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User	Non-lab (CLIA Waived) and lab professionals (CLIA certified)	same

Performance Data:

Performance data presented in the predicate 510(k) submission (K233611) has all the required data to support the labeling change to the existing device to include the SPOTFIRE R/ST Panel Mini in the intended use for SPOTFIRE RSP Pos & Neg Controls, and the packaging change to combine Positive and Negative controls in a single kit box. No additional performance data are required as the SPOTFIRE RSP Pos & Neg Controls have not been changed, the assay consumables are identical for the SPOTFIRE R/ST Panel used to collect original performance data and the SPOTFIRE R Panel Mini. In addition, the targets reported in the SPOTFIRE R/ST Panel Mini are a subset of the SPOTFIRE R/ST Panel.

Results and Conclusion:

Based upon the substantial equivalence characteristics listed in **Table 5** and the original performance data (K233611), MMQCI has determined that the proposed change to the intended use (the addition of the SPOTFIRE R/ST Panel Mini assay), and the packaging to contain Positive and Negative controls in the same kit box, supports substantial equivalence to the predicate device K233611, SPOTFIRE RSP Pos & Neg Controls.