April 13, 2023

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

Re: K230868
Trade/Device Name: SPOTFIRE RSP Pos & Neg Controls, SPOTFIRE RSP Positive Control, 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: March 28, 2023
Received: March 29, 2023

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 (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,

Joseph Briggs -S

Joseph Briggs
Deputy Branch Chief
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230868

Device Name
SPOTFIRE® RSP Pos & Neg Controls, SPOTFIRE® RSP Positive Control, and SPOTFIRE® RSP Negative Control

Indications for Use *(Describe)*
SPOTFIRE® RSP Positive Control is intended for use (as applicable) as an external positive 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, Adenovirus, seasonal Coronavirus, Coronavirus SARS-CoV-2, 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 (SPOTFIRE® R Panel) and BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini (SPOTFIRE® R Panel Mini) assays performed on the BIOFIRE® SPOTFIRE® System. SPOTFIRE® RSP Positive Control is comprised of in vitro RNA transcripts and stabilizing solution and is designed for and intended to be used solely with the SPOTFIRE R Panel and the SPOTFIRE R Panel Mini assays. This product is not intended to replace manufacturer internal controls provided with the device.

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, Adenovirus, seasonal Coronavirus, Coronavirus SARS-CoV-2, 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 (SPOTFIRE® R Panel) and BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini (SPOTFIRE® R Panel Mini) assays performed on the BIOFIRE® SPOTFIRE® System. SPOTFIRE® RSP Negative Control is comprised of a solution that does not contain target analytes and is designed for and intended to be used solely with the SPOTFIRE R Panel and SPOTFIRE R Panel Mini assays. This product is not intended to replace manufacturer internal controls provided with the device.

Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.

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 5: Special 510 (k) Summary

510(k) Number:

Purpose for submission: Change to existing device (reference K221253) to include the BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini (SPOTFIRE R Panel Mini) in the intended use for 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: March 28, 2023

Device

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

Predicate Device

K221253: SPOTFIRE® RSP Pos & Neg Controls
SPOTFIRE® RSP Positive Control
SPOTFIRE® RSP Negative Control

Proposed Change:

The specific change to the existing device is the inclusion of the SPOTFIRE R Panel Mini in the intended use for SPOTFIRE RSP Pos & Neg Controls, with subsequent updates of the Indications of Use (FDA Form 3881), and Package Inserts for SPOTFIRE RSP Positive Control and SPOTFIRE RSP Negative Control. No other changes have been made to the original device referenced in K221253.

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Description of Modified Device (inclusion of SPOTFIRE R Panel Mini):

SPOTFIRE RSP Pos & Neg Controls, P/N M425, is a quality control panel consisting of 2 separate kits of ready-to-use, liquid controls, SPOTFIRE RSP Positive Control (Positive Control), P/N M42638 and SPOTFIRE RSP Negative Control (Negative Control), P/N M42738. 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 pathogens detected by the SPOTFIRE R Panel (Table 1) and SPOTFIRE R Panel Mini (Table 2) on the SPOTFIRE System and is specifically designed for and intended to be used solely with the SPOTFIRE R Panel and SPOTFIRE R Panel Mini assays on the SPOTFIRE System. The Negative Control contains buffer and preservatives with no RNA. Each liquid control of SPOTFIRE RSP Pos & Neg Controls, P/N M425, is processed separately according to the SPOTFIRE R Panel and SPOTFIRE R Panel Mini assay manufacturer's Instructions for Use for Quality Control testing.

Table 1. Respiratory pathogens detected by the SPOTFIRE R Panel

Viruses	**Bacteria**
Adenovirus	*Bordetella parapertussis*
Coronavirus 229E, HKU1, OC43, NL631	*Bordetella pertussis*
Coronavirus SARS-CoV-2	*Chlamydia pneumoniae*
Human Metapneumovirus	*Mycoplasma pneumoniae*
Human Rhinovirus/ Enterovirus	
Influenza A Virus, subtypes H1-2009, H3	
Influenza B Virus	
Parainfluenza Virus serotypes 1-42	
Respiratory Syncytial Virus	

1. Reported as seasonal Coronavirus (undifferentiated).
2. Reported as Parainfluenza Virus (undifferentiated).

Table 2. Respiratory viruses detected by the SPOTFIRE R Panel Mini

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 Panel Mini

SPOTFIRE® RSP Positive Control:

SPOTFIRE® RSP Positive Control is intended for use (as applicable) as an external positive 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*, Adenovirus, seasonal Coronavirus, Coronavirus SARS-CoV-2, 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 (SPOTFIRE® R Panel) and BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini (SPOTFIRE® R Panel Mini) assays performed on the BIOFIRE® SPOTFIRE® System. SPOTFIRE® RSP Positive Control is comprised of *in vitro* RNA transcripts and stabilizing solution and is designed for and intended to be used solely with the SPOTFIRE R Panel and the SPOTFIRE R Panel Mini assays. This product is not intended to replace manufacturer internal controls provided with the device.

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*, Adenovirus, seasonal Coronavirus, Coronavirus SARS-CoV-2, 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 (SPOTFIRE® R Panel) and BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini (SPOTFIRE® R Panel Mini) assays performed on the BIOFIRE® SPOTFIRE® System. SPOTFIRE® RSP Negative Control is comprised of a solution that does not contain target analytes and is designed for and intended to be used solely with the SPOTFIRE R Panel and SPOTFIRE R Panel Mini assays. This product is not intended to replace manufacturer internal controls provided with the device.

Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.

Note: Product insert includes the Rx symbol.

Substantial Equivalence

Maine Molecular Quality Controls, Inc. (MMQCI) proposes that changes made to the labeling for SPOTFIRE RSP Pos & Neg Controls do not impact substantial equivalence to the predicate device (K221253), SPOTFIRE® RSP Pos & Neg Controls. The manufacturing processes and

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components used to manufacture SPOTFIRE RSP Pos & Neg Controls are the same as those of the predicate device. In addition, the targets detected by the SPOTFIRE R Panel Mini are included in the SPOTFIRE R Panel.

Table 3. Substantial Equivalence of Predicate Device

Characteristic	**Modified Device: SPOTFIRE RSP Pos & Neg Controls**	**Predicate Device: K221253 SPOTFIRE RSP Pos & Neg Controls**
Intended Use	External assayed quality control to monitor in vitro lab nucleic acid test using the SPOTFIRE R Panel and SPOTFIRE R Panel Mini, performed on the SPOTFIRE System.	Original 510(k) did not include the SPOTFIRE R Panel Mini
Labeling	SPOTFIRE (R) Panel Mini included in the Product Insert only, no changes to kit or tube labels	SPOTFIRE (R) Panel Mini not included in the Product Insert
Physical format	Ready-to-Use Liquid	Same
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	Original 510(k) did not include the SPOTFIRE R Panel Mini. This panel contains 5 viral targets that are included in the SPOTFIRE R Panel
Pathogens contained in the control panel	Respiratory	same
User	Non-lab (CLIA Waived) and lab professionals (CLIA certified)	same

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Performance Data:

Performance data presented in the 510(k) submission (K221253) has all required data to support the change to existing the device to include the SPOTFIRE R Panel Mini in the intended use for SPOTFIRE RSP Pos & Neg Controls. 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 Panel used to collect original performance data and the SPOTFIRE R Panel Mini added to the intended use of the device. In addition, the targets reported in the SPOTFIRE R Panel Mini are a subset of the SPOTFIRE R Panel.

Results and Conclusion:

Based upon the substantial equivalence characteristics listed in Table 3 and the original performance data (K221253), MMQCI has determined that the proposed change to the intended use (the addition of the SPOTFIRE R Panel Mini assay), supports substantial equivalence to the predicate device K221253, SPOTFIRE RSP Pos & Neg Controls.