February 03, 2023

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

Re: K221253
Trade/Device Name: 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: April 29, 2022
Received: May 2, 2022

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).

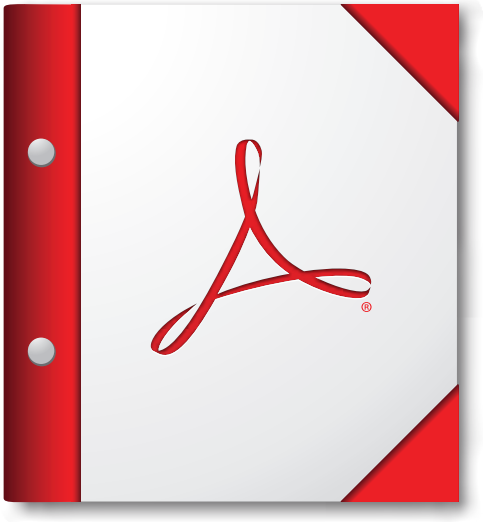
Sincerely,

Joseph Briggs -S

Digitally signed by Joseph Briggs -S
Date: 2023.02.03 14:24:15 -05'00'

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



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Section 5: 510 (k) Summary

510(k) Number: K221253

Purpose for submission: New product

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 25, 2022; updated January 20, 2023

Device

Device Trade Name:	SPOTFIRE® RSP Pos & Neg Controls, comprised of SPOTFIRE® RSP Positive Control and SPOTFIRE® RSP 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
Panel:	Microbiology - 83
Product code:	PMN

Predicate Device

A. K202196; BioFire RP2.1/RP2.1*plus* Control Panel M441

Device Description

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

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RNA segments of all the respiratory pathogens detected by the BIOFIRE® SPOTFIRE® Respiratory (R) Panel on the BIOFIRE® SPOTFIRE® System (see **Table 1** below) and is specifically designed for and intended to be used solely with the SPOTFIRE R Panel assay 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 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, NL63[1]	*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 1-4[2]	
Respiratory Syncytial Virus	

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

Device Intended Use of SPOTFIRE® RSP Pos & Neg Controls

SPOTFIRE® RSP Positive Control

SPOTFIRE® RSP Positive Control is intended for use 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 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 BIOFIRE SPOTFIRE R Panel. 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.

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SPOTFIRE® RSP Negative Control

SPOTFIRE® RSP Negative Control is intended for use 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 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 BIOFIRE SPOTFIRE R Panel. 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.

Substantial Equivalence

Maine Molecular Quality Controls, Inc. (MMQCI) proposes that SPOTFIRE RSP Pos & Neg Controls are substantially equivalent to MMQCI's product, BioFire RP2.1/RP2.1*plus* Control Panel M441 (K202196). The manufacturing processes and components used to manufacture SPOTFIRE RSP Pos & Neg Controls are similar to those of the predicate device. SPOTFIRE RSP Pos & Neg Controls are used as quality controls for assays on the BIOFIRE SPOTFIRE System, while the predicate device is used for assays on the BioFire FilmArray System. However, the 2 systems encompass similar technology; on board extraction and nested multiplexed PCR with assessment of endpoint melting curve data. The rationale for equivalence is listed in **Table 3** below.

Table 3. Substantial Equivalence of Predicate Device

Characteristic	**Candidate Device: SPOTFIRE RSP Pos & Neg Controls**	**Predicate Device: BioFire RP2.1/RP2.1*plus* Control Panel M441 (K202196)**
Intended Use	External assayed quality control to monitor in vitro lab nucleic acid test	Same
Physical format	Ready-to-Use Liquid	Same
Directions for Use	Process like patient sample	Same
Composition	Synthetic RNA transcripts	Same

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Assay steps monitored	Reverse transcription, amplification, detection, identification	Same
Test System	SPOTFIRE	FilmArray 2.0 or FilmArray Torch
Number of targets monitored in one assay	Multiple	Same
Pathogens contained in the control panel	Respiratory	Respiratory
User	Non-lab (CLIA Waived) and lab professionals (CLIA certified)	Lab professionals (CLIA certified)

Summary of Performance Data

Three (3) lots of SPOTFIRE RSP Positive Control and 3 of SPOTFIRE RSP Negative Control, 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, different operators, pouch lots, instruments, test sites, and testing over time were incorporated to challenge manufacture processes and product performance. External and internal studies were performed by testing the 3 lots with the SPOTFIRE R Panel assay on the SPOTFIRE System (BioFire Diagnostics) to generate a total of 361 test results.

For the external performance study, 5 near-patient clinical sites (the SPOTFIRE R Panel intended use environment) tested samples of each of the 3 lots of SPOTFIRE RSP Positive Controls and SPOTFIRE RSP Negative Controls as they would test controls during normal operations, using 25 SPOTFIRE R Panel pouch lots, incorporating multiple operators and instruments for a total of 232 tests, including 7 with Invalid results which were repeated. The internal study was performed by testing samples of each of the 3 lots at MMQCI (Saco, Maine) on different days with 3 pouch lots by 3 operators for a total of 129 tests (3 controls with Invalid results were repeated). One of the pouch lots used at the MMQCI site was also used at a clinical site.

Results and Conclusions:
Of the total 361 tests performed, there were 10 Invalid results which were repeated for 351 valid test results. The Invalid results included instrument errors (3) and failed internal pouch controls (7). The Invalid samples were re-tested according to BioFire instructions and were not included in the Percent Correct analysis in **Table 2** below. Of the 351 valid results, 350 results were correct. One SPOTFIRE RSP Positive Control failed due to false negative results for 3 analytes.

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Reproducibility of SPOTFIRE RSP Positive and RSP Negative Control at 6 sites, across 27 unique pouch lots, 3 control lots, on multiple instruments by multiple operators is acceptable according to predetermined criteria with an overall correct result rate of 99.7%. Test results demonstrate robust performance across 6 testing sites.

Table 2. SPOTFIRE RSP Positive and Negative Controls, all sites.

Summary of Reproducibility Test Results: External and Internal Sites								
Total Tests	Invalid*	Correct Positive Control Result	Incorrect Positive Control Result	Percent Correct Positive Control	Correct Negative Control Result	Incorrect Negative Control Result	Percent Correct Negative Control	Total Percent Correct
361	10	171	1	99.3%	179	0	100%	99.7%

*The Invalid samples were not included in the Percent Correct analysis.

External Site Testing Details

A total of 232 samples of SPOTFIRE RSP Positive and RSP Negative Control were tested at 5 near-patient clinical sites, the BIOFIRE SPOTFIRE R Panel intended use environment. The sites were asked to follow the SPOTFIRE R Panel IUO Quick Guide to run the controls as they would during normal operations, e.g. training a new operator, receiving new shipments of R Panel test kits, receiving new or repaired instrumentation, and whenever the test kits have been stored at an incorrect temperature. It was recommended a negative quality control sample be run at least monthly to monitor for environmental contamination. The amount of QC a site performed was based on the number of operators they had and the amount of SPOTFIRE R Panel testing their site performed.

Three lots of SPOTFIRE RSP Positive Control (A02NOV20, B06NOV20, C10NOV20) and 4 lots of SPOTFIRE RSP Negative Control (F09JUL19, D11MAR20, H05MAY20, C13MAY20) were tested on 25 SPOTFIRE R Panel pouch lots across the 5 sites, incorporating multiple operators and instruments. Of the 232 controls tested, there were 7 with Invalid results which were repeated for a total of 225 controls with valid results. Of the 7 Invalid results, 4 were due to failed internal pouch controls and 3 were due to instrument errors.

Results and Conclusion:

Out of 225 tests with valid results, the correct analytes were detected (for positive controls) or not detected (for negative controls) in 224 tests, for an overall success rate of 99.6% (**Table 4**). One SPOTFIRE RSP Positive Control failed due to false negative results for 3 analytes. The predetermined acceptance criteria for reproducibility were met. SPOTFIRE RSP Positive Control and RSP Negative Control performed robustly at the 5 external test sites across 25 pouch lots on the SPOTFIRE System, incorporating multiple operators.

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Table 4. Summary of External Reproducibility Results for 3 Control Lots at 5 Clinical Sites

Summary of External Results for 3 Lots of SPOTFIRE RSP Pos & Neg Controls									
Site	**Total Tests**	**Invalid**	**Correct Positive Control Result**	**Incorrect Positive Control Result**	**Percent Correct Positive Control**	**Correct Negative Control Result**	**Incorrect Negative Control Result**	**Percent Correct Negative Control**	**Total Percent Correct**
1	26	0	13	0	100%	13	0	100%	100%
2	33	1	13	0	100%	19	0	100%	100%
3	120	4	53	1	98.1%	62	0	100%	99.1%
4	44	1	21	0	100%	22	0	100%	100%
5	9	1	8	0	100%	NA	NA	NA	100%
All Sites	232	7*	108	1	99.1%	116	0	100%	99.6%

*Invalid results were not included in percent correct.

Internal Site Testing Details

Run-to-run Precision Testing at MMQCI: Of the total 361 reproducibility tests, 129 SPOTFIRE RSP Positive Control and SPOTFIRE RSP Negative Control samples were tested on 21 different days at MMQCI's facility in Saco, Maine. Three lots of Positive Control (A02NOV20, B06NOV20, C10NOV20) and 3 lots of Negative Control (F09JUL19, D11MAR20, H05MAY20) were tested on 3 SPOTFIRE R pouch lots, incorporating 4 operators and 1 SPOTFIRE instrument (**Table 5**). One of the pouch lots was also used for the external site testing.

Results and conclusions:
Of the 129 results, 3 were Invalid which were repeated for a total of 126 valid results. All 126 of the valid results were correct for an overall correct result rate of 100%. Predetermined acceptance criteria for reproducibility were met. SPOTFIRE RSP Positive Control and SPOTFIRE RSP Negative Control performed robustly on 21 different days at MMQCI across 3 pouch lots on 1 SPOTFIRE instrument, incorporating 4 operators.

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Table 5. SPOTFIRE RSP Positive Control and SPOTFIRE RSP Negative Control: Reproducibility results at MMQCI.

Summary of Precision Testing for 3 SPOTFIRE RSP Control Lots at MMQCI						
Control	**Control Lot#**	**No. of Tests**	**Invalid ***	**Correct Results**	**Incorrect Results**	**Percent Correct**
SPOTFIRE RSP Positive Control	A02NOV20	23	2	21	0	100%
SPOTFIRE RSP Positive Control	B06NOV20	21	0	21	0	100%
SPOTFIRE RSP Positive Control	C10NOV20	22	1	21	0	100%
SPOTFIRE RSP Negative Control	F09JUL19	21	0	21	0	100%
SPOTFIRE RSP Negative Control	D11MAR20	21	0	21	0	100%
SPOTFIRE RSP Negative Control	H05MAY20	21	0	21	0	100%
*Invalid results were not included in percent correct.	*TOTAL*	129	3	126	0	100%

The above information supports the substantial equivalence of the SPOTFIRE RSP Positive and Negative Controls to the predicate device.