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

June 24, 2021

Re: K202196
Trade/Device Name: BioFire RP2.1/RP2.1plus Control Panel M441
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 30, 2020
Received: August 5, 2020

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,

Kristian Roth, Ph.D.
Deputy Director (Acting)
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202196

Device Name
BioFire RP2.1/RP2.1plus Control Panel M441

Indications for Use *(Describe)*

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 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.

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.

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Section 5: 510 (k) Summary

510(k) Number:

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:	July 30, 2020

Device

Device Trade Name:	BioFire RP2.1/RP2.1*plus* Control Panel M441
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

K173171; FilmArray RP2/RP2*plus* Control Panel, P/N 315

Device Description

BioFire RP2.1/RP2.1*plus* Control Panel M441, P/N M441, is a quality control panel consisting of 2 ready-to-use, liquid controls, BioFire RP2.1/RP2.1*plus* Positive (Positive Control) and BioFire RP2.1/RP2.1*plus* Negative, (Negative Control). The Positive Control contains non-infectious surrogate control material; a solution of synthetic RNA transcripts in buffer, stabilizers and preservatives. The RNA carries segments of all respiratory pathogens detected by the BioFire® Respiratory Panel 2.1 (RP2.1), BioFire® Respiratory Panel 2.1*plus* (RP2.1*plus)*, and BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) assays (Table 1. below) on the BioFire® FilmArray systems, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). BioFire RP2.1/RP2.1*plus* Negative contains buffer and preservatives with no RNA. Each liquid control of BioFire RP2.1/RP2.1*plus*

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Control Panel M441 is processed separately according to BioFire RP2.1, RP2.1*plus*, and RP2.1-EZ assays manufacturer's Instructions for Use for patient samples (nasopharyngeal swabs) obtained from individuals suspected of respiratory tract infection and placed in Viral Transport Media (VTM)).

Table 1. Respiratory pathogens detected by BioFire RP2.1, RP2.1*plus,* and RP2.1-EZ assays.

Respiratory Pathogens	
Adenovirus	Influenza B
Coronavirus 229E	Parainfluenza Virus 1
Coronavirus HKU1	Parainfluenza Virus 2
Coronavirus NL63	Parainfluenza Virus 3
Coronavirus OC43	Parainfluenza Virus 4
Middle East Respiratory Syndrome Coronavirus*	Respiratory Syncytial Virus
Severe Acute Respiratory Syndrome Coronavirus 2	*Bordetella parapertussis (IS001)*
Human Metapneumovirus	*Bordetella pertussis (ptxP)*
Human Rhinovirus/ Enterovirus	*Chlamydia pneumoniae*
Influenza A, subtypes H1, H1-2009, H3	*Mycoplasma pneumoniae*

*Detected by BioFire RP2.1*plus* assay only.

Device Intended Use

BioFire RP2.1/RP2.1*plus* 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 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* (RP2.1*plus)* and BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) assays performed on BioFire FilmArray® systems. BioFire RP2.1/RP2.1*plus* Positive control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the BioFire RP2.1, BioFire RP2.1*plus* and BioFire RP2.1-EZ assays. This product is not intended to replace manufacturer controls provided with the device.

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Substantial Equivalence

BioFire RP2.1/RP2.1*plus* Control Panel M441 is manufactured using processes and a formula identical to those for MMQCI's quality control FilmArray RP2/RP2*plus* Control Panel (K173171), except for the addition of SARS-CoV-2 synthetic RNA. The Intended Use of the 2 control panels is the same.

Characteristic	**Candidate Device: BioFire RP2.1/RP2.1plus Control Panel M441**	**Predicate Device: FilmArray RP2/RP2plus Control Panel (K173171)**
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
Assay steps monitored	Reverse transcription, amplification, detection, identification	Same
Number of targets monitored in one assay	Multiple	Same
Pathogens contained in the control panel	Respiratory, including SARS-CoV-2	Same, not SARS-CoV-2

Summary Performance Data

Three lots of BioFire RP2.1/RP2.1*plus* Control Panel M441, BioFire RP2.1/RP2.1*plus* Positive (Positive Control), P/N M44321, and BioFire RP2.1/RP2.1*plus* Negative (Negative Control), P/N M44221, were manufactured by MMQCI. Internal and external studies were performed by testing the 3 lots with the BioFire® RP2.1/RP2.1*plus* assay on BioFire FilmArray Systems.

The internal study was performed by testing the 3 lots at MMQCI (Saco, Maine) over 2.5 weeks with 3 pouch lots by 3 operators. An external study was performed at an independent U.S. facility to assess performance of the BioFire RP2.1/RP2.1*plus* Control Panel M441 by independent operators on a large number of BioFire FilmArray instruments. The external performance study tested the 3 lots of BioFire RP2.1/RP2.1*plus* Control Panel M441 over a period of 8 days using 3 BioFire FilmArray pouch lots, incorporating multiple operators and instruments. Two of the BioFire pouch lots used at MMQCI were also used for testing at the external site, for a total of 4 pouch lots used across the 2 sites.

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Results and Conclusion:

All BioFire RP2.1/RP2.1*plus* Control Panel M441 controls were correctly detected in the internal and external studies. There was one Invalid result.

Table 2. Summary of All Test Results: Internal and External Sites

Number of 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
2	172	1*	86	0	100%	85	0	100%

*The Invalid result was not included in percent correct.

External Site Testing

A total of 52 BioFire RP2.1/RP2.1*plus* Control Panel M441 samples were tested between April 29, 2020 and May 8, 2020 at an external test site, independent of MMQCI. Three lots of Positive Control (D24APR20, F28APR20 C29APR20) and three lots of Negative Control (D11MAR20, F09JUL19, L22JUL19) were tested on three BioFire pouch lots, incorporating multiple operators and BioFire FilmArray instruments. All 52 controls tested were successful on the first attempt except for 1 Invalid pouch.

Results and Conclusion:

All BioFire RP2.1/RP2.1*plus* Positive controls and all BioFire RP2.1/RP2.1*plus* Negative controls gave correct results, with 1 Invalid pouch. BioFire RP2.1/RP2.1*plus* Control Panel M441 performed robustly when tested at the external site across 3 pouch lots, on multiple BioFire FilmArray 2.0 and Torch instruments/ modules, incorporating multiple operators.

Table 3. Summary of External Results for 3 Control Lots

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
52	1*	26	0	100%	25	0	100%

* The Invalid sample was not included in the Percent Correct analysis.

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Precision Testing

Precision was demonstrated by testing 3 lots of BioFire RP2.1/RP2.1*plus* Positive control and 3 lots of BioFire RP2.1/RP2.1*plus* Negative control at MMQCI's facility in Saco, Maine over 20 days with 3 pouch lots by 3 operators using two FilmArray® 2.0 instruments. All BioFire RP2.1/RP2.1*plus* Control Panel M441 controls were correctly detected. No Invalid results were seen.

Results and Conclusion:

BioFire RP2.1/RP2.1*plus* Control Panel M441 is a robust and reproducible control panel across multiple control and reagent lots.

Table 4. Summary of Precision Testing for 3 Control Lots at MMQCI

Control	**Control Lot #**	**No. of Tests**	**Invalid**	**Correct Results**	**Incorrect Results**	**Percent Correct**
FilmArray RP2.1/RP2.1*plus* Positive	D24APR20	20	0	20	0	100%
FilmArray RP2.1/RP2.1*plus* Positive	F28APR20	20	0	20	0	100%
FilmArray RP2.1/RP2.1*plus* Positive	C29APR20	20	0	20	0	100%
FilmArray RP2.1/RP2.1*plus* Negative	D11MAR20	20	0	20	0	100%
FilmArray RP2.1/RP2.1*plus* Negative	F09JUL19	20	0	20	0	100%
FilmArray RP2.1/RP2.1*plus* Negative	L22JUL19	20	0	20	0	100%
	TOTAL	120	0	120	0	100%