November 24, 2017

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

Re: K173171
Trade/Device Name: FilmArray RP2/RP2plus Control Panel
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed quality control material for clinical microbiology assays
Regulatory Class: Class II
Product Code: PMN
Dated: September 27, 2017
Received: September 29, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173171

Device Name
FilmArray RP2/RP2plus Control Panel

Indications for Use *(Describe)*
FilmArray RP2/RP2plus Control Panel is intended for use 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 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, *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae* by BioFire's FilmArray® RP2 and RP2plus assays on the FilmArray® 2.0 or the FilmArray® Torch Systems. FilmArray RP2/RP2plus Control Panel is composed of synthetic RNA designed for and intended to be used solely with the FilmArray® RP2 and RP2plus assays. This product is not intended to replace manufacturer controls provided with the test system.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

23 Mill Brook Road
Mill Brook Business Park
Saco, Maine 04072
www.mmqci.com
Phone: 207-885-1072
Fax: 207-885-1079

510 (k) Summary

510(k) Number: K173171

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: September 27, 2017

Device

Device Trade Name:	FilmArray RP2/RP2*plus* Control Panel
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

K161573; FilmArray RP EZ Control Panel M265, Maine Molecular Quality Controls, Inc.

Device Description

FilmArray RP2/RP2*plus* Control Panel, P/N M315, is a quality control panel consisting of controls, FilmArray RP2/RP2*plus* Positive (Positive Control), P/N M31721, and FilmArray RP2/RP2*plus* Negative, (Negative Control), P/N M31621. The Positive Control contains non-infectious surrogate control material; a solution of synthetic RNA transcripts in buffers, stabilizers and preservatives. The RNA carries segments of all respiratory pathogens detected by the FilmArray® RP2 and RP2*plus* assays (Table 1. below) on the FilmArray® 2.0 or FilmArray® Torch systems. The RNA in the Negative Control is non-specific RNA in buffers, stabilizers and preservatives. Each liquid control of FilmArray RP2/RP2*plus* Control Panel M265 is processed

23 Mill Brook Road
Mill Brook Business Park
Saco, Maine 04072
www.mmqci.com
Phone: 207-885-1072
Fax: 207-885-1079

separately according to FilmArray® RP2 and RP2*plus* 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 FilmArray RP2 and RP2*plus* assays

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

*Detected by FilmArray RP2*plus* assay only.

Device Intended Use

FilmArray RP2/RP2*plus* Control Panel is intended for use 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 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, *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae* by BioFire's FilmArray® RP2 and RP2*plus* assays on the FilmArray® 2.0 or the FilmArray® Torch Systems. FilmArray RP2/RP2*plus* Control Panel is composed of synthetic RNA designed for and intended to be used solely with the FilmArray® RP2 and RP2*plus* assays. This product is not intended to replace manufacturer controls provided with the test system.

23 Mill Brook Road
Mill Brook Business Park
Saco, Maine 04072
www.mmqci.com
Phone: 207-885-1072
Fax: 207-885-1079

Substantial Equivalence

Characteristic	**Candidate Device: FilmArray RP2/RP2*plus* Control Panel**	**Predicate Device: FilmArray RP EZ Control Panel M265 (K161573)**
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

Summary Performance Data

All Test Results

Three lots of FilmArray RP2/RP2*plus* Control Panel, FilmArray RP2/RP2*plus* Positive (Positive Control), P/N M31721, and FilmArray RP2/RP2*plus* Negative (Negative Control), P/N M31621, were manufactured by MMQCI. Internal and external studies were performed by testing the 3 lots with the FilmArray® RP2*plus* assay on the FilmArray System.

The internal study was performed by testing the 3 lots at MMQCI (Saco, Maine) over 20 days with 4 pouch lots by four operators. An external study was performed to assess performance of the FilmArray RP2/RP2*plus* Control Panel in a clinical setting. The external performance study tested the 3 lots of FilmArray RP2/RP2*plus* Control Panel at 3 CLIA-certified clinical sites over a period of 10 days using 3 FilmArray pouch lots, incorporating multiple operators.

All FilmArray RP2/RP2*plus* Positive control respiratory pathogen analytes were correctly detected in the internal and external study (Correct Positive Control Result). All but 1 FilmArray Negative Control gave Correct Negative Control Results of no respiratory pathogens detected for both studies. The incorrect Negative Control result was a false positive HRV/ EV seen when Negative Control was tested at MMQCI.

23 Mill Brook Road
Mill Brook Business Park
Saco, Maine 04072
www.mmqci.com
Phone: 207-885-1072
Fax: 207-885-1079

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
4	301	0	150	0	100%	150	1	99.4%

External Site Testing

A total of 180 FilmArray RP2/RP2*plus* Control Panel samples were tested between July 2017 and August 2017 at 3 clinical sites. Three lots of Positive Control (C11MAY17, G12JUN17, B21JUN17) and three lots of Negative Control (B11MAY17, F12JUN17, A21JUN17) were tested on three different FilmArray RP2 pouch lots (testing was performed using an IUO pouch module that reported all analyte results; this is equivalent to the RP2*plus* product) across the 3 sites, incorporating multiple operators. Three Positive Controls and three Negative Controls were run per day/per site and testing spanned a period of 10 days. Not all testing days were consecutive. All 180 controls tested were successful on the first attempt (180/180, 100.0%).

Results and Conclusion:
All FilmArray RP2/RP2*plus* Positive controls and all FilmArray RP2/RP2*plus* Negative controls gave correct results. Controls performed robustly at all 3 clinical sites using multiple pouch lots and incorporating multiple operators.

Table 3. Summary of External Results for 3 Control Lots								
External 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**
1	60	0	30	0	100%	30	0	100%
2	60	0	30	0	100%	30	0	100%
3	60	0	30	0	100%	30	0	100%
All Sites	180	0	90	0	100%	90	0	100%

23 Mill Brook Road
Mill Brook Business Park
Saco, Maine 04072
www.mmqci.com
Phone: 207-885-1072
Fax: 207-885-1079

Reproducibility

NOTE: The FilmArray 2.0 is a random access instrument. Therefore, 'run' refer to replicates tested on the same day.

Within-run Testing: Within-run reproducibility was demonstrated by 1 operator testing 1 lot each of FilmArray RP2/RP2*plus* Positive and FilmArray RP2/RP2*plus* Negative with 1 lot of FilmArray RP2 pouches on the FilmArray 2.0, each within one day at MMQCI.
Conclusion: All results were correct and reproducible.

Table 4. Summary of Within-run Reproducibility

Control	Control Lot #	Number of Tests	Date of Testing	Pouch Lot	Correct Results
FilmArray RP2/RP2*plus* Positive	G12JUN17A	6	8/23/2017	606817	6/6
FilmArray RP2/RP2*plus* Negative	F12JUN17A	6	8/24/2017	606817	6/6

Precision Testing: Precision was demonstrated by testing 3 lots of FilmArray RP2/RP2*plus* Positive control and 3 lots of FilmArray RP2/RP2*plus* Negative control at MMQCI over 20 days with 4 pouch lots by 4 operators using two FilmArray® 2.0 instruments. All FilmArray RP2/RP2*plus* Positive control analytes were correctly detected. No Invalid results were seen. All FilmArray RP2/RP2*plus* Negative results were correct except for one false positive HRV/ EV.

Conclusion: FilmArray RP2/RP2*plus* Control Panel is a reproducible control set across control lots and reagent lots.

Table 5. 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/RP2*plus* Positive	C11MAY17	20	0	20	0	100%
FilmArray RP2/RP2*plus* Positive	G12JUN17	20	0	20	0	100%
FilmArray RP2/RP2*plus* Positive	B21JUN17	20	0	20	0	100%
FilmArray RP2/RP2*plus* Negative	B11MAY17	20	0	20	0	100%
FilmArray RP2/RP2*plus* Negative	F12JUN17	20	0	20	0	100%
FilmArray RP2/RP2*plus* Negative	A21JUN17	21	0	20	1	95.2%
	TOTAL	121	0	120	1	99.2%