DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 2, 2016

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

Re: K161573
Trade/Device Name: FilmArray RP EZ Control Panel M265
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed quality control material for clinical microbiology assays
Regulatory Class: Class II (Special Controls)
Product Code: PMN
Dated: June 6, 2016
Received: June 7, 2016

Dear Ms. 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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Steven R. Gitterman -S

for 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)*
K161573

Device Name
FilmArray RP EZ Control Panel M265

Indications for Use *(Describe)*

FilmArray RP EZ Control Panel M265 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 H3, Influenza A subtype H1-2009, Influenza B, Parainfluenza Virus, Respiratory Syncytial Virus, *Bordetella pertussis*, *Chlamydophila pneumoniae*, and *Mycoplasma pneumoniae* on the FilmArray RP EZ assay performed on the FilmArray systems. FilmArray RP Positive Control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the FilmArray RP 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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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: K161573

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: May 31, 2016

Device

Device Trade Name:	FilmArray RP EZ Control Panel M265, model M265
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

DEN150058; Amplichek II, Bio-Rad Laboratories

Device Description

FilmArray RP EZ Control Panel M265, P/N M265, is a quality control panel consisting of 2 controls, FilmArray RP EZ Positive Control, P/N M266, and FilmArray RP EZ Negative Control, P/N M267. 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 RP EZ assay (Table 1. below) on the FilmArray 2.0 EZ Configuration system. The RNA in the Negative Control is non-specific RNA in buffers, stabilizers and preservatives. Each liquid control of FilmArray RP EZ Control Panel M265 is processed separately according to FilmArray RP EZ assay manufacturer's Instructions for Use for patient samples (nasopharyngeal swabs

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(NPS) obtained from individuals suspected of respiratory tract infection and placed in Viral Transport Media (VTM)).

Table 1. Respiratory pathogens detected by FilmArray RP EZ assay

Respiratory Pathogens	
Adenovirus	Influenza A H1-2009
Coronavirus	Influenza B
Human Metapneumovirus	Parainfluenza Virus
Human Rhinovirus/ Enterovirus	Respiratory Syncytial Virus
Influenza A	*Bordetella pertussis*
Influenza A subtype H1	*Chlamydophila pneumoniae*
Influenza A subtype H3	*Mycoplasma pneumoniae*

Device Intended Use

FilmArray RP EZ Control Panel M265 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 H3, Influenza A subtype H1-2009, Influenza B, Parainfluenza Virus, Respiratory Syncytial Virus, *Bordetella pertussis*, *Chlamydophila pneumoniae*, and *Mycoplasma pneumoniae* on the FilmArray RP EZ assay performed on the FilmArray systems. FilmArray RP Positive Control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the FilmArray RP EZ assay. This product is not intended to replace manufacturer controls provided with the device.

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Substantial Equivalence

Characteristic	**Candidate Device: FilmArray RP EZ Control Panel M265 (K161573)**	**Predicate Device Amplichek II (DEN150058)**
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	Intact microorganisms
Assay Steps Monitored	Extraction, reverse transcription, amplification, detection, identification	Same except does not monitor extraction (new device not encapsulated)
Number of targets monitored in one assay	Multiple	Same

Summary Performance Data

All Test Results

Three lots of FilmArray RP EZ Control Panel M265, FilmArray RP EZ Positive Control and FilmArray RP EZ Negative Control, were manufactured and tested using the FilmArray RP EZ assay on the FilmArray instrument 2.0 EZ Configuration system to confirm performance. The lots were manufactured incorporating variables including multiple key component lots, different operator and different days over four months.

An internal study was performed by testing the 3 lots at MMQCI (Saco, Maine) over multiple days with 4 reagent lots by one operator. An external study was performed to assess the ability of the intended user to test the FilmArray RP EZ Control Panel M265 in a CLIA-waived setting. The external performance study tested the 3 lots of FilmArray RP EZ Control Panel M265 at 2 CLIA-waived sites and 1 external site under simulated CLIA-waived conditions over a period of 10 days using 3 FilmArray reagent lots, incorporating multiple operators.

All FilmArray RP EZ Positive Control respiratory pathogen analytes were correctly detected in the internal and external study (Correct Positive Control Result). All but 2 FilmArray RP EZ Negative Controls gave Correct Negative Control Results of no respiratory pathogens detected. There were 3 Invalid results caused by internal control pouch failures and 2 false positive results. It is not possible to determine the cause of the 2 false positive results. However, since the results were from 2 different control lots and 2 different pouch lots at the same testing site, environmental contamination is possible, especially since testing occurred during flu season.

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Table 1. Summary of All Test Results								
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	271	3	129	0	100%	137	2	98.6%

*The 3 Invalid samples were re-tested according to BioFire instructions and were not included in the Percent Correct analysis.

External Site Testing

Three lots of FilmArray RP EZ Control Panel M265, FilmArray RP EZ Positive Control and FilmArray RP EZ Negative Control, were manufactured by MMQCI. They were tested by the FilmArray RP EZ assay on the FilmArray instrument 2.0 EZ Configuration system at two CLIA-waived clinical settings and one simulated CLIA-waived test setting where users were screened to have training and educational backgrounds consistent with those in the CLIA-waived testing environment.

Testing consisted of three positive and three negative controls run per day, and spanned a period of 10 days (total of 60 control runs per site). Multiple operators participated in testing at each of the three locations. Three lots each of external control material and three lots of RP EZ pouches were tested across all sites.

A total of 182 external controls were tested (91 positive and 91 negative). Two tests were excluded from final data analysis due to Invalid results caused by internal pouch control failures. Data for the remaining 180 control tests are shown below.

Table 2. Summary of External Test 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	61	1	30	0	100%	30	0	100%
2	61	1	30	0	100%	30	0	100%
3	60	0	30	0	100%	28	2	93.3%
All Sites	182	2	90	0	100%	88	2	97.8%

*The 2 Invalid samples were re-tested according to BioFire instructions and were not included in the Percent Correct analysis.

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Reproducibility

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

Within-run Testing: Within-run reproducibility was demonstrated by 1 operator testing 2 lots of FilmArray RP EZ Control Panel M265 with 1 lot of FilmArray RP EZ pouches on the FilmArray 2.0, each within one day. All results were correct and reproducible.

Table 3. Summary of Within-run Reproducibility Results

Control	Control Lot#	No. of Tests	Date of Testing	Pouch Lot	Correct Results
FilmArray RP EZ Positive Control	A06JAN16A	6	1-7-16	239115	6/6
FilmArray RP EZ Negative Control	M41DEC15A	5	12-31-15	239115	5/5

Lot-to-Lot Testing: Lot-to-lot reproducibility was demonstrated by testing 3 lots of FilmArray RP EZ Positive Control using the same pouch lot. All results were correct and reproducible.

Table 4. Summary of Lot-to-Lot Testing

Control Lot #	Number of Tests	Pouch Lot	Correct Results
M40DEC15A	4	238915	4/4
A28DEC15A	3	238915	3/3
A06JAN16A	5 (1 Invalid)	238915	4/4

Precision Testing: Precision was demonstrated by testing 3 lots of FilmArray RP EZ Positive Control and 3 lots of FilmArray RP EZ Negative Control at MMQCI over multiple days with 4 reagent lots by one operator using one FilmArray 2.0 instrument. All FilmArray RP EZ Positive Control respiratory pathogen analytes were correctly detected. One test was excluded from final data analysis due to Invalid results caused by an internal pouch control failure.

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 RP EZ Positive Control	M40DEC15A	12	0	12	0	100%
FilmArray RP EZ Positive Control	A28DEC15A	13	0	13	0	100%
FilmArray RP EZ Positive Control	A06JAN16A	15	1	14	0	100%
FilmArray RP EZ Negative Control	A29OCT15B	16	0	16	0	100%
FilmArray RP EZ Negative Control	M41DEC15A	16	0	16	0	100%
FilmArray RP EZ Negative Control	A04JAN16A	17	0	17	0	100%
	TOTAL	*89*	*0*	*88*	*0*	*100 %*

*The Invalid sample was re-tested according to BioFire instructions and was not included in the Percent Correct analysis.