May 3, 2019

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

Re: K190222
Trade/Device Name: FilmArray Pneumonia/Pneumonia*plus* 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: January 15, 2019
Received: February 5, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for

Uwe Scherf, 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)*
K190222

Device Name
FilmArray Pneumonia/Pneumonia*plus* Control

Indications for Use *(Describe)*
FilmArray Pneumonia/Pneumonia*plus* Control 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 bacteria: *Acinetobacter calcoaceticus-baumannii complex*, *Enterobacter cloacae complex*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Moraxella catarrhalis*, Proteus spp., *Pseudomonas aeruginosa*, *Serratia marcescens*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Chlamydia pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*; antimicrobial resistance genes: CTX-M, IMP, KPC, mecA/C and MREJ, NDM, OXA-48 like, VIM; and viruses: Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Parainfluenza Virus and Respiratory Syncytial Virus on the FilmArray Pneumonia Panel or Pneumonia Panel plus assays performed on FilmArray systems. FilmArray Pneumonia/ Pneumonia*plus* Control is composed of synthetic DNA and RNA designed for and intended to be used solely with the FilmArray Pneumonia Panel and FilmArray Pneumonia Panel plus assays. This product is not intended to replace manufacturer internal 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.

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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: January 14, 2019

Device

Device Trade Name:	FilmArray Pneumonia/Pneumonia*plus* Control, P/N M340
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 Pneumonia/Pneumonia*plus* Control, P/N M340, is a quality control panel consisting of 2 controls, FilmArray Pneumonia/Pneumonia*plus* Positive (Positive Control), P/N M34235, and FilmArray Pneumonia/Pneumonia*plus* Negative, (Negative Control), P/N M34135. The Positive Control contains non-infectious surrogate control material; a solution of synthetic DNA and RNA in buffers, stabilizers and preservatives. The DNA and RNA in the Positive Control carries nucleic acid corresponding to the genome segments of all the respiratory pathogens and antimicrobial resistance genes detected and identified by the FilmArray® Pneumonia Panel and Pneumonia Panel *plus* assays (see Table 1. below) on the FilmArray® systems. The Negative Control contains only buffers, stabilizers and preservatives. Each liquid control of FilmArray Pneumonia/Pneumonia*plus*

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Control is processed separately according to FilmArray® Pneumonia Panel or Pneumonia Panel *plus* assays manufacturer's Instructions for Use for patient samples (Sputum) obtained from individuals suspected of lower respiratory tract infection. Each tube of control contains sufficient liquid for a single use.

Table 1. Respiratory pathogens and antimicrobial resistance genes detected by FilmArray®Pneumonia Panel & Pneumonia Panel *plus* assays.

Bacteria	
Acinetobacter calcoaceticus-baumannii complex	*Pseudomonas aeruginosa*
Enterobacter cloacae complex	*Serratia marcescens*
Escherichia coli	*Staphylococcus aureus*
Haemophilus influenzae	*Streptococcus agalactiae*
Klebsiella aerogenes	*Streptococcus pneumoniae*
Klebsiella oxytoca	*Streptococcus pyogenes*
Klebsiella pneumoniae group	*Chlamydia pneumoniae*
Moraxella catarrhalis	*Legionella pneumophila*
Proteus spp.	*Mycoplasma pneumoniae*
Antimicrobial Resistance Genes	
CTX-M	NDM
IMP	OXA-48 like
KPC	VIM
mecA/C and MREJ	
Viruses	
Adenovirus	Influenza B
Coronavirus	Middle East Respiratory Syndrome Coronavirus*
Human Metapneumovirus	Parainfluenza Virus
Human Rhinovirus/Enterovirus	Respiratory Syncytial Virus
Influenza A	

*Detected by FilmArray Pneumonia Panel *plus* assay only.

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Device Intended Use

FilmArray Pneumonia/Pneumonia*plus* Control 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 bacteria: *Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter cloacae* complex, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Moraxella catarrhalis*, *Proteus* spp., *Pseudomonas aeruginosa*, *Serratia marcescens*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Chlamydia pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*; antimicrobial resistance genes: CTX-M, IMP, KPC, *mecA/C* and MREJ, NDM, OXA-48 like, VIM; and viruses: Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Parainfluenza Virus and Respiratory Syncytial Virus on the FilmArray® Pneumonia Panel or Pneumonia Panel *plus* assays performed on FilmArray® systems. FilmArray Pneumonia/Pneumonia*plus* Control is composed of synthetic DNA and RNA specifically designed for and intended to be used solely with the FilmArray Pneumonia Panel and FilmArray Pneumonia Panel *plus* assays. This product is not intended to replace manufacturer controls provided with the device.

Substantial Equivalence

Characteristic	**Candidate Device: FilmArray Pneumonia/Pneumonia*plus* Control**	**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 (swab placed in sputum)	Same (pipette as for VTM)
Composition	Synthetic RNA & DNA	Synthetic RNA transcripts
Assay Steps Monitored	Reverse transcription Amplification, detection, identification	Same
Number of targets monitored in one assay	Multiple	Same

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Summary Performance Data

All Test Results

Three lots of FilmArray Pneumonia/Pneumonia*plus* Control, FilmArray Pneumonia/Pneumonia*plus* Positive (Positive Control), P/N M34235, and FilmArray Pneumonia/Pneumonia*plus* Negative (Negative Control), P/N M34135, were manufactured by Maine Molecular Quality Controls, Inc. (MMQCI). Internal and external studies were performed by testing the 3 lots with the FilmArray Pneumonia Panel *plus* assay on the FilmArray 2.0 or FilmArray Torch systems.

The internal study was performed by testing the 3 lots at MMQCI (Saco, Maine) over 60 days with 3 pouch lots by 3 operators. An external study was performed to assess performance of the FilmArray Pneumonia/Pneumonia*plus* Control in a clinical setting. The external performance study tested the 3 lots of FilmArray Pneumonia/Pneumonia*plus* Control at 3 CLIA-certified clinical sites over a period of 10 days using 3 FilmArray pouch lots, incorporating multiple operators and instruments. Two of the external pouch lots were different from MMQCI lots.

Of 308 tests of FilmArray Pneumonia/Pneumonia*plus* Control, correct results were reported in 300 tests on the first attempt. There were 2 Negative Controls with false positive results and 6 Positive Controls with false negative results. All produced the correct results upon a single retest for an overall correct result rate of 97.4%.

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

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
4	308	0	150	6	96.2%	150	2	98.7%	97.4%

External Site Testing

Of the total 308 tests, 185 FilmArray Pneumonia/Pneumonia*plus* Control samples were tested between July 2018 and September 2018 at 3 clinical sites. Three lots of Positive Control (D04MAY18A, H29MAY18A, C12JUN18A) and three lots of Negative Control (E30APR18A, C18MAY18A, D30MAY18A) were tested on 3 Pneumonia/Pneumonia*plus* pouch lots across the 3 sites, incorporating multiple operators. Three Positive Controls and 3 Negative Controls were run per day/per site over a period of 10 days. Not all testing days were consecutive. Correct results were obtained on the first test of 175 controls. Two Negative Controls gave initial false positive

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results and 3 Positive controls gave initial false negative results. All produced the correct results upon a single retest for an overall correct result rate of 97.3%.

FilmArray Pneumonia/Pneumonia*plus* Control performed reproducibly across 3 clinical sites using multiple pouch lots and incorporating multiple operators.

Table 3. Summary of External Results for 3 Control Lots

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	61	0	30	0	100%	30	1	96.8%	60
2	63	0	30	2	93.8%	30	1	96.8%	60
3	61	0	30	1	96.8%	30	0	100%	60
All Sites	185	0	90	3	96.8%	90	2	97.8%	97.3%

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Internal Site Testing

Of the total 308 tests, 123 FilmArray Pneumonia/Pneumonia*plus* Control samples were tested between July 2018 and September 2018 at MMQCI's facility. Three lots of Positive Control (D04MAY18A, H29MAY18A, C12JUN18A) and 3 lots of Negative Control (E30APR18A, C18MAY18A, D30MAY18A) were tested over 60 days on 3 Pneumonia/Pneumonia*plus* pouch lots, incorporating 3 operators and 2 FilmArray 2.0 instruments. All Positive Controls gave correct results except for 3 which gave false negative results. Repeat tests gave correct results on the first retest. All Negative Controls gave correct results. The overall correct result rate at MMQCI was 97.6%.

Table 4. Summary of Run-to-run Precision Testing for 3 Control Lots at MMQCI

Control	**Control Lot #**	**No. of Tests**	**Invalid**	**Correct Results**	**Incorrect Results**	**Percent Correct**
FilmArray Pneumonia/Pneumonia*plus* Negative	E30APR18A	20	0	20	0	100%
FilmArray Pneumonia/Pneumonia*plus* Negative	C18MAY18A	20	0	20	0	100%
FilmArray Pneumonia/Pneumonia*plus* Negative	D30MAY18A	20	0	20	0	100%
FilmArray Pneumonia/Pneumonia*plus* Positive	D04MAY18A	21	0	20	1	95.2%
FilmArray Pneumonia/Pneumonia*plus* Positive	A29MAY18A	21	0	20	1	95.2%
FilmArray Pneumonia/Pneumonia*plus* Positive	C12JUN18A	21	0	20	1	95.2%
	TOTAL	*123*	*0*	*120*	*3*	*97.6%*

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Internal Site Testing: Repeatability
In addition to the 123 control samples listed in Table 4 above, 7 samples of FilmArray Pneumonia/Pneumonia*plus* Control were tested to demonstrate repeatability.

Within-run Testing: Within-run precision (repeatability) was demonstrated by 1 operator testing 1 lot each of FilmArray Pneumonia/Pneumonia*plus* Positive and FilmArray Pneumonia/Pneumonia*plus* Negative, with 1 lot of FilmArray Pneumonia/Pneumonia*plus* Panel pouches on one FilmArray 2.0, all within one day at MMQCI.

Conclusion: All results were correct.

Table 5. Summary of Within-run Precision at MMQCI

Control	**Control Lot #**	**Number of Tests**	**Date of Testing**	**Pouch Lot**	**Correct Results**
FilmArray Pneumonia / Pneumonia*plus* Positive Control	D04MAY18A	6	8/21/2018	697017	6/6
FilmArray Pneumonia / Pneumonia*plus* Negative Control	E30APR18A	6	8/21/2018	697017	6/6