April 2, 2020

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

Re: K200010
Trade/Device Name: FilmArray BCID2 Control Panel M416
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed Quality Control Material for Clinical Microbiology Assays
Regulatory Class: Class II
Product Code: PMN
Dated: December 30, 2019
Received: January 2, 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.
Branch Chief
Bacterial Multiplex and Medical Counter Measures
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)*
K200010

Device Name

FilmArray BCID2 Control Panel M416

Indications for Use *(Describe)*

FilmArray BCID2 Control Panel M416 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 antimicrobial resistance genes: CTX-M, IMP, KPC, mcr-1, mecA/C, mecA/C and MREJ (MRSA), NDM, OXA-48-like, vanA/B, VIM; Gram positive and Gram negative bacteria: Enterococcus faecalis, Enterococcus faecium, Listeria monocytogenes, Staphylococcus spp., Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus lugdunensis, Streptococcus spp., Streptococcus agalactiae (Group B), Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Acinetobacter calcoaceticus-baumannii complex, Bacteroides fragilis, Enteric bacteria, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus spp., Salmonella spp., Serratia marcescens, Haemophilus influenzae, Neisseria meningitidis, Pseudomonas aeruginosa and Stenotrophomonas maltophilia; and yeast pathogens: Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, and Cryptococcus neoformans/gattii on the BioFire® Blood Culture Identification 2 (BCID2) Panel on the FilmArray® systems. FilmArray BCID2 Control Panel M416 is composed of synthetic DNA specifically designed for and intended to be used solely with the BioFire BCID2 Panel 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.

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
Saco, Maine 04072
www.mmqci.com
Phone: 207-885-1072
Fax: 207-885-1079

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: December 30, 2019

Device

Device Trade Name:	FilmArray BCID2 Control Panel M416, P/N M416
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

K190222; FilmArray Pneumonia/Pneumonia*plus* Control, Maine Molecular Quality Controls, Inc.

Device Description

FilmArray BCID2 Control Panel M416, P/N M416, is a quality control panel consisting of 2 controls, FilmArray BCID2 Positive Control, P/N M41718, and FilmArray BCID2 Negative Control, P/N M41818. The Positive Control contains non-infectious surrogate control material; a solution of synthetic DNA in buffers, stabilizers and preservatives. The DNA in the Positive Control carries nucleic acid corresponding to the genome segments of all the pathogens and antimicrobial resistance genes detected and identified by the BioFire® Blood Culture Identification 2 (BCID2) Panel assay (see Table 1. below) on the FilmArray® systems. The Negative Control contains only buffers, stabilizers and preservatives. Each liquid control of FilmArray BCID2 Control Panel M416 is processed separately according to BioFire BCID2 Panel assay manufacturer's Instructions for Use for patient samples (positive blood cultures)

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

obtained from individuals suspected of sepsis. Each tube of control contains sufficient liquid for a single use.

Table 1. Pathogens and antimicrobial resistance genes found in FilmArray BCID2 Control Panel M416, detected by BioFire BCID2 Panel assay.

Antimicrobial resistance genes	
CTX-M	*mecA/C* and MREJ (MRSA)
IMP	NDM
KPC	OXA-48-like
mcr-1	*vanA/B*
mecA/C	VIM
Gram Positive Bacteria	
Enterococcus faecalis	*Streptococcus* spp.
Enterococcus faecium	*Streptococcus agalactiae* (Group B)
Listeria monocytogenes	*Streptococcus pneumoniae*
Staphylococcus spp.	*Streptococcus pyogenes* (Group A)
Staphylococcus aureus	
Staphylococcus epidermidis	
Staphylococcus lugdunensis	
Gram Negative Bacteria	
Acinetobacter calcoaceticus-baumannii complex	Enteric bacteria
Bacteroides fragilis	*Proteus* spp.
Enteric bacteria	*Salmonella* spp
Enterobacter cloacae complex	*Serratia marcescens*
Escherichia coli	*Haemophilus influenzae*
Klebsiella aerogenes	*Neisseria meningitidis*
Klebsiella oxytoca	*Pseudomonas aeruginosa*
Klebsiella pneumoniae group	*Stenotrophomonas maltophilia*
Yeast	
Candida albicans	*Candida parapsilosis*
Candida auris	*Candida tropicalis*
Candida glabrata	*Cryptococcus neoformans/gattii*
Candida krusei	

Device Intended Use

FilmArray BCID2 Control Panel M416 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 antimicrobial resistance genes: CTX-M, IMP, KPC, *mcr-1*, *mecA/C*, *mecA/C* and *MREJ* (MRSA), NDM, OXA-48-like, *vanA/B*, VIM; Gram positive and Gram negative bacteria: *Enterococcus faecalis*, *Enterococcus faecium*, *Listeria monocytogenes*, *Staphylococcus* spp., *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Streptococcus* spp., *Streptococcus agalactiae* (Group B), *Streptococcus pneumoniae*, *Streptococcus pyogenes* (Group A), *Acinetobacter calcoaceticus-baumannii* complex, *Bacteroides fragilis*, Enteric bacteria, *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group,

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

Proteus spp., *Salmonella* spp., *Serratia marcescens*, *Haemophilus influenzae*, *Neisseria meningitidis*, *Pseudomonas aeruginosa* and *Stenotrophomonas maltophilia*; and yeast pathogens: *Candida albicans*, *Candida auris*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, *Candida tropicalis*, and *Cryptococcus neoformans/gattii* on the BioFire® Blood Culture Identification 2 (BCID2) Panel assay on FilmArray® systems. FilmArray BCID2 Control Panel M416 is composed of synthetic DNA specifically designed for and intended to be used solely with the BioFire BCID2 Panel assay. This product is not intended to replace manufacturer controls provided with the device.

Substantial Equivalence

Characteristic	**Candidate Device: FilmArray BCID2 Control Panel M416**	**Predicate Device: FilmArray Pneumonia/Pneumonia*plus* Control (K190222)**
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 (Pipette from blood culture tube)	Process like patient sample (Pipette from sputum or BAL tube)
Composition	Synthetic DNA	Synthetic DNA, and RNA transcripts
Assay Steps Monitored	Amplification, detection, identification	Same plus reverse transcription
Number of targets monitored in one assay	Multiple, >30 targets	Same, >30 targets

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

Summary Performance Data

Precision: Reproducibility Testing Summary of Internal and External sites

Three lots of FilmArray BCID2 Control Panel M416 consisting of FilmArray BCID2 Positive Control and FilmArray BCID2 Negative Control were manufactured by MMQCI. Reproducibility studies were performed by testing the 3 control lots with the BioFire BCID2 Panel assay on FilmArray systems at MMQCI and 3 clinical laboratories. The lots were manufactured and tested such that routine variables including multiple lots of key manufacturing components, different operators, pouch lots, instruments, test sites, and testing over time were incorporated in the study.

Internal testing at MMQCI (Saco, Maine) was performed by testing 20 samples of each of the 3 lots on different days over approximately 6 weeks, with 3 pouch lots by 4 operators for a total of 122 (2 repeats) tests.

The external performance study to assess the FilmArray BCID2 Control Panel M416 in a clinical setting was performed by testing 10 samples of each of the 3 lots of BCID2 Control Panel M416 on different days at 3 CLIA-certified clinical sites using 3 FilmArray pouch lots and incorporating multiple operators for a total of 186 (6 repeats) tests.

Summary Results and Conclusions:

Of the total 307 tests performed for the Reproducibility study, there were 300 correct results, positive and negative as listed in Table 2. There were 2 Invalid results and 5 incorrect Positive control results. The samples that gave Invalid results were re-tested according to BioFire instructions and were not included in the Percent Correct analysis in the table below. The incorrect Positive controls were all correct upon retesting. The predetermined acceptance criteria for the FilmArray BCID2 Control Panel M416 Reproducibility study, internal and external, were met for an overall correct result rate of 98.4%.

Table 2. FilmArray BCID2 Control Panel M416: Reproducibility results, all sites.

Summary of Reproducibility Test Results at MMQCI and 3 Clinical Laboratory 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
307	2	150	5	96.8%	150	0	100.0%	98.4%

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