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

July 22, 2022

Re: K203680
Trade/Device Name: BioFire JI Control Panel M420
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 15, 2020
Received: June 14, 2022

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,

Noel J. Gerald, Ph.D.
Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203680

Device Name
BioFire JI Control Panel M420

Indications for Use *(Describe)*
BioFire JI Control Panel M420 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 gram-positive and gram-negative bacteria: Anaerococcus prevotii/vaginalis, Clostridium perfringens, Cutibacterium avidum/granulosum, Enterococcus faecalis, Enterococcus faecium, Finegoldia magna, Parvimonas micra, Peptoniphilus, Peptostreptococcus anaerobius, Staphylococcus aureus, Staphylococcus lugdunensis, Streptococcus spp., Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes, Bacteroides fragilis, Citrobacter, Enterobacter cloacae complex, Escherichia coli, Haemophilus influenzae, Kingella kingae, Klebsiella aerogenes, Klebsiella pneumoniae group, Morganella morganii, Neisseria gonorrhoeae, Proteus spp., Pseudomonas aeruginosa, Salmonella spp., and Serratia marcescens, antimicrobial resistance genes: CTX-M, IMP, KPC, mecA/C and MREJ (MRSA), NDM, OXA-48-like, vanA/B, VIM, and yeast pathogens: Candida and Candida albicans on the BioFire JI Panel assay on the BioFire systems. BioFire JI Control Panel M420 is composed of synthetic DNA specifically designed for and intended to be used solely with the BioFire JI 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.

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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:	December 15, 2020

Device

Device Trade Name:	BioFire JI Control Panel M420, P/N M420
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

K200010; FilmArray BCID2 Control Panel M416, P/N M416, Maine Molecular Quality Controls, Inc.

Device Description

BioFire JI Control Panel M420, P/N M420, is a quality control panel consisting of 2 controls, BioFire JI Positive Control, P/N M42118, and JI Negative Control, P/N M42218. 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® Joint Infection (JI) Panel assay (see Table 1. below) on the BioFire® systems. The Negative Control contains buffers, stabilizers and preservatives. Each liquid control of BioFire JI Control Panel M420 is processed separately according to the BioFire JI Panel assay manufacturer's Instructions for Use for patient samples (synovial fluid) obtained from individuals suspected of infection. Each tube of control contains sufficient liquid for a single use.

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Table 1. Pathogens and antimicrobial resistance genes found in BioFire JI Control Panel M420, detected by BioFire JI Panel assay.

	Positive Control	Negative Control
Gram Positive Bacteria		
Anaerococcus prevotii/vaginalis	Detected	Not Detected
Clostridium perfringens	Detected	Not Detected
Cutibacterium avidum/granulosum	Detected	Not Detected
Enterococcus faecalis	Detected	Not Detected
Enterococcus faecium	Detected	Not Detected
Finegoldia magna	Detected	Not Detected
Parvimonas micra	Detected	Not Detected
Peptoniphilus	Detected	Not Detected
Peptostreptococcus anaerobius	Detected	Not Detected
Staphylococcus aureus	Detected	Not Detected
Staphylococcus lugdunensis	Detected	Not Detected
Streptococcus spp.	Detected	Not Detected
Streptococcus agalactiae	Detected	Not Detected
Streptococcus pneumoniae	Detected	Not Detected
Streptococcus pyogenes	Detected	Not Detected
Gram Negative Bacteria		
Bacteroides fragilis	Detected	Not Detected
Citrobacter	Detected	Not Detected
Enterobacter cloacae complex	Detected	Not Detected
Escherichia coli	Detected	Not Detected
Haemophilus influenzae	Detected	Not Detected
Kingella kingae	Detected	Not Detected
Klebsiella aerogenes	Detected	Not Detected
Klebsiella pneumoniae group	Detected	Not Detected
Morganella morganii	Detected	Not Detected
Neisseria gonorrhoeae	Detected	Not Detected
Proteus spp.	Detected	Not Detected
Pseudomonas aeruginosa	Detected	Not Detected
Salmonella spp.	Detected	Not Detected
Serratia marcescens	Detected	Not Detected
Antimicrobial resistance genes		
CTX-M	Detected	N/A
IMP	Detected	N/A
KPC	Detected	N/A
mecA/C and MREJ (MRSA)	Detected	N/A
NDM	Detected	N/A
OXA-48-like	Detected	N/A
vanA/B	Detected	N/A
VIM	Detected	N/A
Yeast		
Candida	Detected	Not Detected
Candida albicans	Detected	Not Detected

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Device Intended Use

BioFire JI Control Panel M420 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 Gram positive and Gram negative bacteria: *Anaerococcus prevotii/vaginalis, Clostridium perfringens, Cutibacterium avidum/granulosum, Enterococcus faecalis, Enterococcus faecium, Finegoldia magna, Parvimonas micra, Peptoniphilus, Peptostreptococcus anaerobius, Staphylococcus aureus, Staphylococcus lugdunensis, Streptococcus* spp., *Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes, Bacteroides fragilis, Citrobacter, Enterobacter cloacae complex, Escherichia coli, Haemophilus influenzae, Kingella kingae, Klebsiella aerogenes, Klebsiella pneumoniae* group, *Morganella morganii, Neisseria gonorrhoeae, Proteus* spp., *Pseudomonas aeruginosa, Salmonella* spp., and *Serratia marcescens*, antimicrobial resistance genes: CTX-M, IMP, KPC, *mecA/C* and MREJ (MRSA), NDM, OXA-48-like, *vanA/B*, VIM, and yeast pathogens: *Candida and Candida albicans* on the BioFire JI Panel assay on the BioFire systems. BioFire JI Control Panel M420 is composed of synthetic DNA specifically designed for and intended to be used solely with the BioFire JI Panel assay. This product is not intended to replace manufacturer controls provided with the device.

Substantial Equivalence

Maine Molecular Quality Controls, Inc. (MMQCI) proposes that BioFire JI Control Panel M420 is substantially equivalent to currently marketed medical device FilmArray BCID2 Control Panel M416 (K200010). BioFire JI Control Panel M420 is manufactured using the same processes and formulation as for MMQCI's quality control, FilmArray BCID2 Control Panel M416.

Characteristic	**Candidate Device: BioFire JI Control Panel M420**	**Predicate Device: FilmArray BCID2 Control Panel M416 (K200010)**
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 synovial fluid)	Process like patient sample (Pipette from blood culture)
Composition	Synthetic DNA	Same
Assay Steps Monitored	Amplification, detection, identification	Same
Number of targets monitored in one assay	Multiple, >30 targets	Same, >30 targets

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Summary Performance Data

Three lots of BioFire JI Control Panel M420, consisting of BioFire JI Positive Control and BioFire JI Negative Control, were manufactured by MMQCI. 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 to challenge performance. External and internal studies were performed by testing the 3 lots with the BioFire® JI Panel assay on BioFire FilmArray Systems. The external performance study was performed by testing 10 samples of each of the 3 lots of BioFire JI Control Panel M420 on different days at 3 CLIA-certified clinical sites using 3 FilmArray pouch lots, incorporating multiple operators for a total of 181 tests (1 Invalid result was repeated). The internal reproducibility study was performed by testing 20 samples of each of the 3 lots at MMQCI (Saco, Maine) on different days with 3 pouch lots by 3 operators for a total of 120 tests.

Results and Conclusions:

Of the total 301 tests performed for the Reproducibility study, there were 300 correct results, positive and negative as listed in Table 2, and 1 Invalid result. The sample that gave an Invalid result was re-tested according to BioFire instructions and was not included in the Percent Correct analysis in the table below.

Reproducibility of BioFire JI Control Panel M420 at 4 sites, across 3 pouch lots, 3 control lots, on multiple instruments by multiple operators is acceptable according to predetermined criteria with an overall correct result rate of 100%. Test results demonstrate robust performance across 4 testing sites.

Table 2. BioFire JI Control Panel M420: Reproducibility results, all sites.

Summary of Reproducibility Test Results: 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
301	1	150	0	100%	150	0	100%	100%

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

External Site Testing Details

Of the total 301 reproducibility tests, 181 BioFire JI Control Panel M420 samples were tested at 3 clinical sites. Three lots of BioFire JI Positive Control (D19DEC19A, D23DEC19A, E27DEC19A) and 3 lots of BioFire JI Negative Control (C28NOV18F, A14JUN19G, F29OCT19D) were tested on 3 BioFire JI Panel pouch lots across the 3 sites, incorporating multiple operators and instruments. The laboratories were instructed to run 3 Positive and 3 Negative controls, for each lot, per day on 10 different days. Valid results were obtained for 180 controls. Of the 181 controls tested, 1 gave an Invalid result and was retested according to BioFire Instructions for Use. Correct results were obtained for the retest. The Invalid result was not included in the Percent Correct analysis in the table below.

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Results and Conclusion:
Out of 180 tests with valid pouch controls, the correct analytes were detected (for positive controls) or not detected (for negative controls) in all 180 tests, for an overall success rate of 100% (Table 3). Predetermined acceptance criteria for reproducibility were met. BioFire JI Control Panel M420 performed robustly at the 3 external test sites across 3 pouch lots on 19 BioFire FilmArray 2.0 and Torch instruments/ modules, incorporating multiple operators.

Table 3. BioFire JI Control Panel M420: Summary of Reproducibility Results for 3 Control Lots at 3 Clinical Sites

Summary of External Results for 3 Control Lots of BioFire JI Control Panel M420									
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	1*	30	0	100%	30	0	100%	100%
2	60	0	30	0	100%	30	0	100%	100%
3	60	0	30	0	100%	30	0	100%	100%
All Sites	181	1*	90	0	100%	90	0	100%	100%

*Invalid result was not included in percent correct.

Internal Site Testing Details

Run-to-run Precision Testing at MMQCI: Of the total 301 reproducibility tests, 120 BioFire JI Control Panel M420 samples were tested over February and March of 2020 at MMQCI's facility. Each control was tested 20 times on 20 different days. Three lots of Positive Control (D19DEC19A, D23DEC19A, E27DEC19A) and 3 lots of Negative Control (C28NOV18F, A14JUN19G, F29OCT19D) were tested on 3 BioFire JI pouch lots, incorporating 3 operators and 2 FilmArray 2.0 instruments (Table 4).

Results and conclusions:
All Controls gave correct results for an overall correct result rate of 100%. Predetermined acceptance criteria for reproducibility were met. BioFire JI Control Panel M420 performed robustly on 20 different days at MMQCI across 3 pouch lots on 2 BioFire FilmArray 2.0 instruments, incorporating 3 operators.

Table 4. FilmArray BCID2 Control Panel M416: Reproducibility results at MMQCI.

Summary of Precision Testing for 3 JI Control Lots at MMQCI						
Control	**Control Lot #**	**No. of Tests**	**Invalid**	**Correct Results**	**Incorrect Results**	**Percent Correct**
BioFire JI Negative Control	C28NOV18F	20	0	20	0	100%
BioFire JI Negative Control	A14JUN19G	20	0	20	0	100%
BioFire JI Negative Control	F29OCT19D	20	0	20	0	100%
BioFire JI Positive Control	D19DEC19A	20	0	20	0	100%
BioFire JI Positive Control	D23DEC19A	20	0	20	0	100%
BioFire JI Positive Control	E27DEC19A	20	0	20	0	100%
	TOTAL	120	0	120	0	100%

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Matrix Effects

Human Synovial fluid used for the study: Single Donor Human Synovial Fluid, Part Number IRHUSYNS1ML, Company: Innovative Research

The matrix of the BioFire JI Control Panel M420 is synthetic, which allows for reproducible manufacturing and stability, provides a non-infectious material for the laboratory staff and carries the control DNA through the extraction process. Since the matrix is not identical to that of the routine JI assay sample, synovial fluid, a test was performed to investigate the effect of the matrix on the assay. Equal volumes of the same concentration of gDNA *Streptococcus pneumoniae, strain TCH8431* (BEI Resources, P/N HM-145D) were spiked into 270µL of BioFire JI Control Panel M420 matrix and 270µL of contrived patient matrix (Human Synovial Fluid; Innovative Research), then tested on the BioFire JI Panel assay in triplicate. Criteria to be met are correct calls for the spiked simulated clinical sample and spiked matrix.

Results and Conclusions:
The same expected calls were obtained for the spiked human synovial fluid (simulated clinical sample) and spiked JI matrix (Detected for *Streptococcus spp. and S. pneumoniae*, Not Detected for all other assays)
As indicated in the summary data table below (Table 11), the BioFire JI Control Panel M420 matrix has no effect on the assay.

Table 5. Matrix Testing for BioFire JI Control Panel M420 with Human Synovial fluid

Pathogen Analyte	**Spiked BEI *S.pneumoniae* Crossing Point (Cp)**							
	MMQCI JI Matrix			**Mean Cp**	**Human Synovial Fluid (SF)**			**Mean Cp**
Streptococcus	10.8	10.4	12.7	11.3	11.4	11.8	11.7	11.6
Spneumoniae	9.3	9.1	10.3	9.6	10.1	10.3	10.2	10.2