



March 14, 2017

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

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

Re: K163522

Trade/Device Name: FilmArray Warrior Control Panel M290
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: December 13, 2016
Received: December 15, 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

Indications for Use

510(k) Number (if known)

K163522

Device Name

FimlArray Warrior Control Panel M290

Indications for Use (Describe)

FilmArray Warrior Control Panel M290 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 *Bacillus anthracis* (Chromosomal element, pXO1, pXO2), *Coxiella burnetii*, *Francisella tularensis*, *Yersinia pestis*, Ebola virus and Marburg virus on the FilmArray NGDS Warrior Panel performed on FilmArray 2.0 systems. FilmArray Warrior Control Panel M290 is composed of synthetic DNA specifically designed for and intended to be used solely with the FilmArray NGDS Warrior Panel assay. This product is not intended to replace manufacturer internal FilmArray NGDS Warrior Panel 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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510 (k) Summary

510(k) Number: K163522

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
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Fax: 207-885-1079
Email Address: jgordon@mmqci.com

Preparation Date: December 12, 2016

Device

Device Trade Name: FilmArray Warrior Control Panel M290, model M290
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 Warrior Control Panel M290, P/N M290, is a quality control panel consisting of 2 controls, FilmArray Warrior Positive Control, P/N M291 and FilmArray Warrior Negative Control, P/N M292. The Positive Control contains non-infectious surrogate control material; a solution of synthetic DNA in buffers, stabilizers and preservatives. The DNA carries segments of all biothreat agents detected by the FilmArray NGDS Warrior Panel assay (Table 1. below) on FilmArray 2.0 systems. The Negative Control is comprised of non-specific DNA in buffers, stabilizers and preservatives. Each liquid control of FilmArray Warrior Control Panel M290 is

processed separately according to FilmArray NGDS Warrior Panel assay manufacturer's Instructions for Use for Blood Samples.

Table 1. Biothreat pathogens detected by FilmArray NGDS Warrior Panel

<i>Bacillus anthracis</i> : Chromosomal element, pXO1, pXO2
<i>Coxiella burnetii</i>
<i>Francisella tularensis</i>
<i>Yersinia pestis</i>
Ebola Virus
Marburg Virus

Device Intended Use

FilmArray Warrior Control Panel M290 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 *Bacillus anthracis* (Chromosomal element, pXO1, pXO2), *Coxiella burnetii*, *Francisella tularensis*, *Yersinia pestis*, Ebola virus and Marburg virus on the FilmArray NGDS Warrior Panel performed on FilmArray 2.0 systems. FilmArray Warrior Control Panel M290 is composed of synthetic DNA specifically designed for and intended to be used solely with the FilmArray NGDS Warrior Panel assay. This product is not intended to replace manufacturer internal FilmArray NGDS Warrior Panel controls provided with the device.

Substantial Equivalence

Characteristic	Candidate Device: FilmArray Warrior Control Panel M290	Predicate Device: FilmArray RP EZ Control Panel M265 (K161573)
Intended Use	External assayed quality control to monitor <i>in vitro</i> lab nucleic acid test	Same
Physical format	Ready-to-Use Liquid	Same
Directions for Use	Process like patient sample	Same
Composition	Synthetic DNA	Synthetic RNA transcripts
Assay Steps Monitored	Amplification, detection, identification	Same plus reverse transcription
Number of targets monitored in one assay	Multiple	Same



Summary Performance Data

All Test Results

Three lots of FilmArray Warrior Control Panel M290, FilmArray Warrior Positive Control and FilmArray Warrior Negative Control, were manufactured by MMQCI and tested using the FilmArray NGDS Warrior Panel on the FilmArray instrument 2.0 system to confirm performance. The lots were manufactured and tested incorporating variables including multiple lots of key manufacturing components, different operators, pouch lots and test sites over six months. Internal and external studies were performed.

The internal study was performed by testing the 3 lots at MMQCI (Saco, Maine) over 23 days with 4 pouch lots by 3 operators. An external study was performed to assess performance of FilmArray Warrior Control Panel M290 in a clinical setting. The external performance study tested the 3 lots of FilmArray Warrior Control Panel M290 at 5 clinical laboratory sites, over 6 months, incorporating 12 unique pouch lots and multiple operators.

All FilmArray Warrior Positive Controls were correctly detected in the internal and external studies (Correct Positive Control Result) except for 2 control samples tested in the external study. One FilmArray Warrior Positive Control test reported Detected for all pathogens except for pXO1 which reported as Not Detected. A second FilmArray Warrior Positive Control test result was Detected for all pathogens except for pXO1 and *Yersinia pestis*, which reported as Not Detected.

All FilmArray Warrior Negative Controls gave Correct Negative Control Results. There were 4 Invalid results caused by internal control pouch failures; 2 for the FilmArray Warrior Positive Control and 2 for the FilmArray Warrior Negative Control.

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
6	434	4	221	2	99.1%	207	0	100%

*The 4 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 Warrior Control Panel M290, FilmArray Warrior Positive Control (Pos) and FilmArray Warrior Negative Control (Neg), were manufactured by MMQCI. They were tested by the FilmArray NGDS Warrior Panel on the FilmArray instrument 2.0 system as follows: Lot 1, Pos C18MAR16/ Neg A02NOV15, was tested at 5 clinical sites over 6 months using 9 pouch lots, incorporating multiple operators. Lots 2 and 3, Pos C01JUL16/ Neg



B01JUL16, and Pos B15JUL16/ Neg A15JUL16, were tested at 2 of the 5 clinical sites on 10 different days, using 3 pouch lots, incorporating multiple operators.

A total of 310 external controls were tested (163 positive and 147 negative). There were no Invalid results. All controls gave correct results except for 2 FilmArray Warrior Positive Controls at 2 different sites. One sample of Lot 2 Pos C01JUL16 gave a Not Detected for pXO1 and *Yersinia pestis* with all other biothreat pathogens detected at Site B, and another sample of Lot 2 Pos C01JUL16 gave a Not Detected for pXO1 with all other biothreat pathogens reported as Detected at Site E for the same pouch lot. The expected percentage of correct results for the clinical study was 95% or greater.

Table 2. Summary of External Test Results for 3 Control Lots								
External Site	Total Tests	Percent Total Correct Results	Correct Positive Control Result	Incorrect Positive Control Result	Percent Correct Positive Control	Correct Negative Control Result	Incorrect Negative control Result	Percent Correct Negative Control
A	41	100%	20	0	100%	21	0	100%
B	104	99.1%	58	1	98.3%	45	0	100%
C	51	100%	26	0	100%	25	0	100%
D	60	100%	31	0	100%	29	0	100%
E	54	98.1%	26	1	96.3%	27	0	100%
All Sites	310	99.4%	161	2	98.8%	147	0	100%

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 1 lot each of FilmArray Warrior Positive Control and FilmArray Warrior Negative Control with 1 lot of NGDS Warrior Panel pouches on the FilmArray 2.0, each within one day at MMQCI. 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 Warrior Positive Control	C01JUL16	6	8-8-16	151216	6/6
FilmArray Warrior Negative Control	B01JUL16	6	8-19-16	151216	6/6

Precision Testing: Precision was demonstrated by testing 3 lots of FilmArray Warrior Positive Control and 3 lots of FilmArray Warrior Negative Control at MMQCI over multiple days with 4 reagent lots by 3 operators using one FilmArray 2.0 instrument. All FilmArray Warrior Positive Control biothreat pathogens were correctly detected. Four tests were excluded from final data analysis due to Invalid results caused by internal pouch control failures.

Table 4. Summary of Precision Testing for 3 Control Lots at MMQCI						
Control	Control Lot #	No. of Tests	Invalid	Correct Results	Incorrect Results	Percent Correct*
FilmArray Warrior Positive Control	C18MAR16	20	0	21	0	100%
FilmArray Warrior Negative Control	A02NOV15	20	0	20	0	100%
FilmArray Warrior Positive Control	C01JUL16	20	0	20	0	100%
FilmArray Warrior Negative Control	B01JUL16	21	1	20	0	100%
FilmArray Warrior Positive Control	B15JUL16	22	2	20	0	100%
FilmArray Warrior Negative Control	A15JUL16	21	1	20	0	100%
	<i>TOTAL</i>	<i>124</i>	<i>4</i>	<i>120</i>	<i>0</i>	<i>100 %</i>

*The 4 Invalid samples were re-tested according to BioFire instructions and were not included in the Percent Correct analysis.

Lot-to-Lot Testing: A subset of the above testing in Table 4 was used to demonstrate Lot-to-lot reproducibility by testing 3 lots of FilmArray Warrior Control Panel M290 using the same pouch lot on the same instrument at MMQCI. All results were correct and reproducible.

Table 5. Summary of Lot-to-Lot Testing				
	Control Lot #	Number of Tests	Pouch Lot	Correct Results
FilmArray Warrior Positive Control	C18MAR16	7	160314	7/7
FilmArray Warrior Negative Control	A02NOV15	7	160314	7/7
FilmArray Warrior Positive Control	C01JUL16	7	160314	7/7
FilmArray Warrior Negative Control	B01JUL16	8 (1 Invalid)	160314	7/7
FilmArray Warrior Positive Control	B15JUL16	7	160314	7/7
FilmArray Warrior Negative Control	A15JUL16	7	160314	7/7