



Food and Drug Administration
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BioFire Diagnostics, LLC
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February 8, 2016

Re: K160068

Trade/Device Name: FilmArray Respiratory Panel (RP) for use with FilmArray Torch
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: II
Product Code(s): OCC, OEM, OOU, OEP, OTG, OZZ, OZX
Dated: January 12, 2016
Received: January 13, 2016

Dear Dr. Kanack:

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 regulations (21 CFR Parts 801 and 809), 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” (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 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 yours,

Tamara V. Feldblyum -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)
K160068

Device Name
FilmArray Respiratory Panel (RP) for Use with FlimArray Torch

Indications for Use (Describe)

The FilmArray Respiratory Panel (RP) is a multiplexed nucleic acid test intended for use with FilmArray systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The following organism types and subtypes are identified using the FilmArray RP: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human Rhinovirus/Enterovirus, Respiratory Syncytial Virus, Bordetella pertussis, Chlamydomphila pneumoniae, and Mycoplasma pneumoniae. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other management decisions. Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test or, lower respiratory tract infection that is not detected by a nasopharyngeal swab specimen. Positive results do not rule out co-infection with other organisms: the agent(s) detected by the Film Array RP may not be the definite cause of disease. Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for Bordetella pertussis, Coronavirus 229E, Coronavirus OC43, Influenza A H1, Influenza A H3, Influenza A H1-2009, Influenza B, Mycoplasma pneumoniae, Parainfluenza Virus 1, Parainfluenza Virus 2, and Parainfluenza Virus 4 were established primarily with retrospective clinical specimens. Performance characteristics for Chlamydomphila pneumoniae were established primarily using contrived clinical specimens.

Due to the genetic similarity between Human Rhinovirus and Enterovirus, the FilmArray RP cannot reliably differentiate them. A positive FilmArray RP Rhinovirus/Enterovirus result should be followed-up using an alternate method (e.g., cell culture or sequence analysis).

The FilmArray RP assay for Coronavirus OC43 may cross-react with some isolates of Coronavirus HKU1. A dual positive result may be due to cross-reactivity or may indicate a co-infection.

Performance characteristics for Influenza A were established when Influenza A 2009 H1N1, A H1, and A H3 were the predominant Influenza A viruses in circulation. Performance of detecting Influenza A may vary if other Influenza A strains are circulating or a novel Influenza A virus emerges. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

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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**Special 510(k) Summary
BioFire Diagnostics, LLC**

FilmArray Respiratory Panel (RP) for use with FilmArray Torch

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by:

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Date Submitted:

January 12, 2016

Trade Name:

FilmArray Respiratory Panel (RP) for use with FilmArray Torch

Classification Name:

21 CFR 866.3980 – Respiratory Viral Panel Multiplex Nucleic Acid Assay
21 CFR 862.2570 – Instrumentation for Clinical Multiplex Test Systems

Predicate Device:

K143080 – FilmArray Respiratory Panel for Use with Multi-Instrument FilmArray System
(FilmArray 2.0)

Intended Use:

The FilmArray Respiratory Panel (RP) is a multiplexed nucleic acid test intended for use with FilmArray systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The following organism types and subtypes are identified using the FilmArray RP: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human Rhinovirus/Enterovirus, Respiratory Syncytial Virus, *Bordetella pertussis*, *Chlamydomphila pneumoniae*, and *Mycoplasma pneumoniae*. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection if used in conjunction with other clinical and

epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other management decisions. Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test or, lower respiratory tract infection that is not detected by a nasopharyngeal swab specimen. Positive results do not rule out co-infection with other organisms: the agent(s) detected by the Film Array RP may not be the definite cause of disease. Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for *Bordetella pertussis*, Coronavirus 229E, Coronavirus OC43, Influenza A H1, Influenza A H3, Influenza A H1-2009, Influenza B, *Mycoplasma pneumoniae*, Parainfluenza Virus 1, Parainfluenza Virus 2, and Parainfluenza Virus 4 were established primarily with retrospective clinical specimens. Performance characteristics for *Chlamydomphila pneumoniae* were established primarily using contrived clinical specimens.

Due to the genetic similarity between Human Rhinovirus and Enterovirus, the FilmArray RP cannot reliably differentiate them. A positive FilmArray RP Rhinovirus/Enterovirus result should be followed-up using an alternate method (e.g., cell culture or sequence analysis).

The FilmArray RP assay for Coronavirus OC43 may cross-react with some isolates of Coronavirus HKU1. A dual positive result may be due to cross-reactivity or may indicate a co-infection.

Performance characteristics for Influenza A were established when Influenza A 2009 H1N1, A H1, and A H3 were the predominant Influenza A viruses in circulation. Performance of detecting Influenza A may vary if other Influenza A strains are circulating or a novel Influenza A virus emerges. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Device Description:

The FilmArray Respiratory Panel (RP) is a multiplexed nucleic acid test for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The FilmArray Respiratory Panel is designed to be used with FilmArray systems (currently FilmArray and FilmArray 2.0). This 510(k) modifies the Device by adding the FilmArray Torch as an additional instrument system for use with the FilmArray Respiratory Panel.

The FilmArray RP pouch contains freeze-dried reagents to perform nucleic acid purification, reverse transcription, and nested, multiplex PCR with DNA melt analysis. FilmArray RP simultaneously conducts 20 tests for the identification of respiratory pathogens from nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections (Table 1). Results from the FilmArray RP test are available within about one hour.

Table 1. Bacteria and Viruses Detected by the FilmArray Respiratory Panel

Viral Respiratory Pathogens
Adenovirus
Coronavirus 229E
Coronavirus HKU1
Coronavirus NL63
Coronavirus OC43
Human Metapneumovirus
Human Rhinovirus/Enterovirus
Influenza A
H1 subtype
H3 subtype
H1-2009 subtype
Influenza B
Parainfluenza Virus 1
Parainfluenza Virus 2
Parainfluenza Virus 3
Parainfluenza Virus 4
Respiratory Syncytial Virus
Bacterial Respiratory Pathogens
<i>Bordetella pertussis</i>
<i>Chlamydophila pneumoniae</i>
<i>Mycoplasma pneumoniae</i>

A test is initiated by loading Hydration Solution and an unprocessed patient nasopharyngeal swab (NPS) specimen (i.e. specimen mixed with Sample Buffer) into the FilmArray RP pouch. The pouch contains all of the reagents required for specimen testing and analysis in a freeze-dried format; the addition of Hydration Solution and specimen/Sample Buffer Mix rehydrates the reagents. After the pouch is prepared, the FilmArray software guides the user through the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, and initiating the run.

FilmArray systems contain a coordinated system of inflatable bladders and seal points, which act on the pouch to control the movement of liquid between the pouch blisters. When a bladder is inflated over a reagent blister, it forces liquid from the blister into connecting channels. Alternatively, when a seal is placed over a connecting channel it acts as a valve to open or close a channel. In addition, electronically controlled pneumatic pistons are positioned over multiple plungers in order to deliver the rehydrated reagents into the blisters at the appropriate times. Two Peltier devices control heating and cooling of the pouch to drive the PCR reactions and the melt curve analysis.

Nucleic acid extraction occurs within the FilmArray pouch using mechanical and chemical lysis followed by purification using standard magnetic bead technology. After extracting and purifying nucleic acids from the unprocessed sample, the FilmArray performs a nested multiplex PCR that is executed in two stages. During the first stage, the FilmArray performs a single, large volume, highly multiplexed reverse transcription PCR (RT-PCR) reaction. The products from first stage PCR are then diluted and combined with a fresh, primer-free master mix and a fluorescent double stranded DNA binding dye (LC Green™ Plus, BioFire Defense, LLC). The

solution is then distributed to each well of the array. Array wells contain sets of primers designed specifically to amplify sequences internal to the PCR products generated during the first stage PCR reaction. The 2nd stage PCR, or nested PCR, is performed in singleplex fashion in each well of the array. At the conclusion of the 2nd stage PCR, the array is interrogated by melt curve analysis for the detection of signature amplicons denoting the presence of specific targets. A digital camera placed in front of the array captures fluorescent images of the PCR reactions and software interprets the data.

The FilmArray Software automatically interprets the results of each DNA melt curve analysis and combines the data with the results of the internal pouch controls to provide a test result for each organism on the panel.

Device Comparison:

The purpose of this submission is to add FilmArray Torch as an additional instrument system for use with the FilmArray Respiratory Panel. There have been no changes to the previously cleared FilmArray Respiratory Panel reagent kit itself. In order to increase throughput capacity, the FilmArray 2.0 was modified to develop the FilmArray Torch by organizing densely packaged instruments (now called FilmArray Torch Modules) into a “tower” configuration having the computer with touchscreen interface incorporated into the system base. Pouches are now inserted horizontally rather than from the top. This configuration allows the FilmArray Torch Modules to be stacked directly on top of each other to minimize system footprint.

The following table compares the FilmArray Respiratory Panel for use with the FilmArray Torch to the previously cleared FilmArray Respiratory Panel for Use with the Multi-instrument FilmArray System (FilmArray 2.0) (K143080). The table outlines the similarities and differences between the two systems.

Table 2. Comparison of the Respiratory Panel for use with FilmArray Torch to the current FilmArray Respiratory Panel for use with FilmArray 2.0.

Element	Modified Device: FilmArray Respiratory Panel for use with FilmArray Torch	Predicate: FilmArray Respiratory Panel for use with the Multi-instrument FilmArray System (FilmArray 2.0) (K143080)
Organisms Detected	Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, Influenza B, Respiratory Syncytial Virus, Human Metapneumovirus, Adenovirus, Parainfluenza 1, Parainfluenza 2, Parainfluenza virus 3, Parainfluenza 4, Human Rhinovirus/Enterovirus, Coronavirus HKU1, Coronavirus NL63, Coronavirus 229E, Coronavirus OC43, <i>Mycoplasma pneumoniae</i> , <i>Chlamydomphila pneumoniae</i> , and <i>Bordetella pertussis</i> .	Same
Analyte	RNA/DNA	Same
Specimen Types	Nasopharyngeal swabs	Same

Element	Modified Device: FilmArray Respiratory Panel for use with FilmArray Torch	Predicate: FilmArray Respiratory Panel for use with the Multi-instrument FilmArray System (FilmArray 2.0) (K143080)
Technological Principles	Nested multiplex RT-PCR followed by high resolution melting analysis to confirm identity of amplified product.	Same
Instrumentation	Single instrument FilmArray system, FilmArray 2.0 system, or FilmArray Torch system	Single instrument FilmArray system or FilmArray 2.0 system
Instrument-Software Communication	Communication for multiple FilmArray Torch Modules travels via Ethernet cable/port.	Same (multiple instruments)
Time to result	About 1 hour	Same
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	Same
Reagent Hydration and Sample Loading	Syringe-based loading procedure or FilmArray Injection Vial-based loading procedure	Same
Sample Preparation Method	Sample Processing is automated in the FilmArray RP pouch.	Same
Reagent Storage	Reagents are stored at room temperature.	Same
Controls	Two controls are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis.	Same
User Complexity	Moderate/Low	Same

Performance Characteristics of FilmArray RP on FilmArray Torch:

Contrived samples containing each FilmArray RP analyte at low positive levels (1x LoD) were tested on three complete FilmArray Torch systems (12 FilmArray Torch Modules per system) over five days (30 replicates per analyte per system) for 90 total replicates per analyte. Reproducible detection at LoD was confirmed for each FilmArray RP analyte with the expected Detected results for $\geq 95.6\%$ of samples tested on FilmArray Torch systems. Agreement with the expected negative results (Not Detected) was 100% for each analyte.

Conclusion:

The intended use and fundamental scientific technology of the FilmArray RP used with the modified device, FilmArray Torch, is unchanged from use of the legally marketed FilmArray RP on FilmArray and FilmArray 2.0 systems. Non-clinical validation studies have established that the performance characteristics of FilmArray RP, including reproducibility, are substantially equivalent on FilmArray, FilmArray 2.0, and FilmArray Torch. These data demonstrate that the device performs as well as the predicate device.