October 27, 2022

BioFire Diagnostics, LLC
Kevin Bourzac
Vice President, Regulatory & Clinical Affairs
515 Colorow Drive
Salt Lake City, Utah 84108

Re: K222601
Trade/Device Name: FilmArray Pneumonia Panel plus
Regulation Number: 21 CFR 866.4001
Regulation Name: A Multiplex Respiratory Panel To Detect And Identify Emerging Respiratory Pathogen(S) And Common Respiratory Pathogens In Human Clinical Specimens
Regulatory Class: Class II
Product Code: QDS
Dated: August 25, 2022
Received: August 29, 2022

Dear Kevin Bourzac:

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,

for

Noel Gerald
Branch Chief
DMD: Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K181324

Device Name
BioFire FilmArray Pneumonia Panel plus

Indications for Use *(Describe)*
The BioFire® FilmArray® Pneumonia Panel plus (BioFire Pneumonia Panel plus) is a multiplexed nucleic acid test intended for use with BioFire® FilmArray® 2.0 (BioFire 2.0) or BioFire® FilmArray® Torch (BioFire Torch) systems for the simultaneous detection and identification of nucleic acids from Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and multiple respiratory viral and bacterial nucleic acids, as well as select antimicrobial resistance genes, in sputum-like specimens (induced or expectorated sputum, or endotracheal aspirates) or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) obtained from individuals meeting MERS-CoV clinical and/or epidemiological criteria.

Testing with BioFire Pneumonia Panel plus should not be performed unless the patient meets clinical and/or epidemiologic criteria for testing suspected MERS-CoV specimens. This includes: clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiological links for which MERS-CoV testing may be indicated.

The following bacteria are reported semi-quantitatively with bins representing approximately 10^4, 10^5, 10^6, or ≥10^7 genomic copies of bacterial nucleic acid per milliliter (copies/mL) of specimen, to aid in estimating relative abundance of nucleic acid from these common bacteria within a specimen:

Bacteria reported with bins of 10^4, 10^5, 10^6, or ≥10^7 copies/mL
- Acinetobacter calcoaceticus-baumannii complex
- Enterobacter cloacae complex
- Escherichia coli
- Haemophilus influenza
- Klebsiella aerogenes
- Klebsiella oxytoca
- Klebsiella pneumoniae group
- Moraxella catarrhalis
- Proteus spp.
- Pseudomonas aeruginosa
- Serratia marcescens
- Staphylococcus aureus
- Streptococcus agalactiae
- Streptococcus pneumoniae
- Streptococcus pyogenes

The following atypical bacteria, viruses, and antimicrobial resistance genes are reported qualitatively:

Atypical Bacteria
- Chlamydia pneumoniae
- Legionella pneumophila
- Mycoplasma pneumoniae

Viruses
- Middle East respiratory syndrome coronavirus (MERS-CoV)

• Adenovirus
• Coronavirus
• Human metapneumovirus
• Human rhinovirus/enterovirus
• Influenza A virus
• Influenza B virus
• Parainfluenza virus
• Respiratory syncytial virus

Antimicrobial Resistance Genes
• CTX-M
• IMP
• KPC
• NDM
• OXA-48-like
• VIM
• mecA/C and MREJ (MRSA)

The detection and identification of specific viral and bacterial nucleic acids from MERS-CoV and other respiratory pathogens, as well as the estimation of relative abundance of nucleic acid from common bacterial analytes, within specimens collected from individuals meeting MERS-CoV clinical and/or epidemiological criteria aids in the differential diagnosis of MERS-CoV infection, if used in conjunction with other clinical and epidemiological information in accordance with the guidelines provided by the appropriate public health authorities.

BioFire Pneumonia Panel plus MERS-CoV positive results are for the presumptive identification of MERS-CoV. The definitive identification of MERS-CoV requires additional testing and confirmation procedures in consultation with the appropriate public health authorities (e.g., local or state public health departments, etc.) for whom reporting is necessary. The diagnosis of MERS-CoV infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of MERS-CoV.

BioFire Pneumonia Panel plus MERS-CoV negative results, even in the context of a BioFire Pneumonia Panel plus positive result for one or more of the common respiratory pathogens, do not preclude MERS-CoV infection and should not be used as the sole basis for patient management decisions. The levels of MERS-CoV that would be present in sputum-like or BAL-like specimens from individuals with early infection and from asymptomatic MERS-CoV carriers are not well understood. A negative BioFire Pneumonia Panel plus MERS-CoV result in an asymptomatic individual does not rule out the possibility of future illness and does not demonstrate that the individual is not infectious.

Viral culture should not be attempted on specimens with positive BioFire Pneumonia Panel plus results for MERS-CoV unless a BSL 3 facility is available to receive and culture specimens.

Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, pathogens below the limit of detection, or in the case of bacterial analytes, present at levels below the lowest reported 10^4 copies/mL bin. Detection of analytes does not rule out co-infection with other organisms; the agent(s) detected by the BioFire Pneumonia Panel plus 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 lower respiratory tract infection.

Detection of bacterial nucleic acid may be indicative of colonizing or normal respiratory flora and may not indicate the causative agent of pneumonia. Semi-quantitative Bin (copies/mL) results generated by the BioFire Pneumonia Panel plus are not equivalent to CFU/mL and do not consistently correlate with the quantity of bacterial analytes compared to CFU/mL. For specimens with multiple bacteria detected, the relative abundance of nucleic acids (copies/mL) may not correlate with the relative abundance of bacteria as determined by culture (CFU/mL). Clinical correlation is advised to determine significance of semi-quantitative Bin (copies/mL) for clinical management.

The antimicrobial resistance gene detected may or may not be associated with the agent(s) responsible for disease. Negative results for these antimicrobial resistance gene assays do not indicate susceptibility to corresponding classes of antimicrobials, as multiple mechanisms of antimicrobial resistance exist.

Antimicrobial resistance can occur via multiple mechanisms. A "Not Detected" result for a genetic marker of antimicrobial resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A "Detected" result for a genetic marker of antimicrobial resistance cannot be definitively linked to the microorganism(s) detected. Culture is required to obtain isolates for antimicrobial susceptibility testing, and BioFire Pneumonia Panel plus results should be used in conjunction with culture results for determination of bacterial susceptibility or resistance.

Due to the genetic similarity between human rhinovirus and enterovirus, the test cannot reliably differentiate them. A positive Rhinovirus/Enterovirus result should be followed up using an alternate method (e.g., cell culture or sequence analysis) if differentiation is required.

Culture is required to identify pathogens not detected by the BioFire Pneumonia Panel plus, to further speciate analytes in genus, complex, or group results if desired, to identify bacterial pathogens present below the 10^4 copies/mL bin if desired, and for antimicrobial susceptibility testing.

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."

Special 510(k) Summary
BioFire Diagnostics, LLC

FilmArray Pneumonia Panel *plus*

Introduction:

Purpose

The content of this Special 510(k) submission is limited to obtaining FDA clearance for the FilmArray Pneumonia Panel *plus* (K181324) with modified labeling to address stability results of the adenovirus2 assay used for the detection of adenovirus C species.

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.

Background

Stability study results showed that the Adenovirus2 assay on Pneumonia Panels (Pneumonia Panel and Pneumonia Panel *plus*) exhibited an increased rate of unexpected Negative results in pouches that were more than 6 months from the date of manufacture (i.e. within 6 months of expiration). As a result of the stability testing, BioFire conducted a voluntary recall of the FilmArray Pneumonia Panels (Part No. RFIT-ASY-0142, RFIT-ASY-0143, RFIT-ASY-0144, and RFIT-ASY-0145) in June 2021 (refer to Recall Event 88117/ Z-2039-2021, Z-2040-2021).

In addition, and as a corrective action, the FilmArray Pneumonia Panel 'Limitations' section in the instructions for use was modified to include new limitations as well as an additional footnote on the analytical Limit of Detection (LoD) table that addresses the detection of adenovirus in the FilmArray Pneumonia Panel within 6 months of expiration. This corrective action was accepted and cleared under special 510(k) K212727.

BioFire would now like to clear the same limitations for the U.S. version of the FilmArray Pneumonia Panel *plus* instructions for use (this submission).

Submitted by:

BioFire Diagnostics, LLC (BioFire)
515 Colorow Drive
Salt Lake City, UT 84108

Contact:

Kevin Bourzac, Ph.D.
Telephone: 801-736-6354, ext. 1358
Fax: 801-588-0507
Email: kevin.bourzac@biomerieux.com

Date Submitted:

August 25, 2022

Trade Name:
FilmArray Pneumonia Panel *plus*

Classification Name:
21 CFR 866.4001 - MERS-CoV and common respiratory pathogens multiplex nucleic acid detection system

Predicate Device:
K181324 – FilmArray Pneumonia Panel *plus*

Intended Use:

The BIOFIRE® FILMARRAY® Pneumonia Panel *plus* (BIOFIRE Pneumonia Panel *plus*) is a multiplexed nucleic acid test intended for use with BIOFIRE® FILMARRAY® 2.0 (BIOFIRE 2.0) or BIOFIRE® FILMARRAY® TORCH (BIOFIRE TORCH) systems for the simultaneous detection and identification of nucleic acids from Middle East respiratory syndrome coronavirus (MERS-CoV) and multiple respiratory viral and bacterial nucleic acids, as well as select antimicrobial resistance genes, in sputum-like specimens (induced or expectorated sputum, or endotracheal aspirates) or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) obtained from individuals meeting MERS-CoV clinical and/or epidemiological criteria.

Testing with BIOFIRE Pneumonia Panel *plus* should not be performed unless the patient meets clinical and/or epidemiologic criteria for testing suspected MERS-CoV specimens. This includes: clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiological links for which MERS-CoV testing may be indicated.

The following bacteria are reported semi-quantitatively with bins representing approximately 10^4, 10^5, 10^6, or ≥10^7 genomic copies of bacterial nucleic acid per milliliter (copies/mL) of specimen, to aid in estimating relative abundance of nucleic acid from these common bacteria within a specimen:

Bacteria reported with bins of 10^4, 10^5, 10^6, or ≥10^7 copies/mL		
Acinetobacter calcoaceticus-baumannii complex	*Klebsiella oxytoca*	*Serratia marcescens*
Enterobacter cloacae complex	*Klebsiella pneumoniae* group	*Staphylococcus aureus*
Escherichia coli	*Moraxella catarrhalis*	*Streptococcus agalactiae*
Haemophilus influenzae	*Proteus* spp.	*Streptococcus pneumoniae*
Klebsiella aerogenes	*Pseudomonas aeruginosa*	*Streptococcus pyogenes*

The following atypical bacteria, viruses, and antimicrobial resistance genes are reported qualitatively:

Atypical Bacteria		
Chlamydia pneumoniae	*Legionella pneumophila*	*Mycoplasma pneumoniae*
Viruses		
Middle East respiratory syndrome coronavirus (MERS-CoV)		
Adenovirus	Human rhinovirus/enterovirus	Parainfluenza virus
Coronavirus	Influenza A virus	Respiratory syncytial virus
Human metapneumovirus	Influenza B virus	
Antimicrobial Resistance Genes		
CTX-M	NDM	*mecA/C* and MREJ (MRSA)
IMP	OXA-48-like	
KPC	VIM	

The detection and identification of specific viral and bacterial nucleic acids from MERS-CoV and other respiratory pathogens, as well as the estimation of relative abundance of nucleic acid from common bacterial analytes, within specimens collected from individuals meeting MERS-CoV clinical and/or epidemiological criteria aids in the differential diagnosis of MERS-CoV infection, if used in conjunction with other clinical and epidemiological information in accordance with the guidelines provided by the appropriate public health authorities.

BIOFIRE Pneumonia Panel *plus* MERS-CoV positive results are for the presumptive identification of MERS-CoV. The definitive identification of MERS-CoV requires additional testing and confirmation procedures in consultation with the appropriate public health authorities (e.g., local or state public health departments, etc.) for whom reporting is necessary. The diagnosis of MERS-CoV infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of MERS-CoV.

BIOFIRE Pneumonia Panel *plus* MERS-CoV negative results, even in the context of a BIOFIRE Pneumonia Panel *plus* positive result for one or more of the common respiratory pathogens, do not preclude MERS-CoV infection and should not be used as the sole basis for patient management decisions. The levels of MERS-CoV that would be present in sputum-like or BAL-like specimens from individuals with early infection and from asymptomatic MERS-CoV carriers are not well understood. A negative BIOFIRE Pneumonia Panel *plus* MERS-CoV result in an asymptomatic individual does not rule out the possibility of future illness and does not demonstrate that the individual is not infectious.

Viral culture should not be attempted on specimens with positive BIOFIRE Pneumonia Panel *plus* results for MERS-CoV unless a BSL 3 facility is available to receive and culture specimens.

Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, pathogens below the limit of detection, or in the case of bacterial analytes, present at levels below the lowest reported 10^4 copies/mL bin. Detection of analytes does not rule out co-infection with other organisms; the agent(s) detected by the BIOFIRE Pneumonia Panel *plus* 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 lower respiratory tract infection.

Detection of bacterial nucleic acid may be indicative of colonizing or normal respiratory flora and may not indicate the causative agent of pneumonia. Semi-quantitative Bin (copies/mL) results generated by the BIOFIRE Pneumonia Panel *plus* are not equivalent to CFU/mL and do not consistently correlate with the quantity of bacterial analytes compared to CFU/mL. For specimens with multiple bacteria detected, the relative abundance of nucleic acids (copies/mL) may not correlate with the relative abundance of bacteria as determined by culture (CFU/mL). Clinical correlation is advised to determine significance of semi-quantitative Bin (copies/mL) for clinical management.

The antimicrobial resistance gene detected may or may not be associated with the agent(s) responsible for disease. Negative results for these antimicrobial resistance gene assays do not indicate susceptibility to corresponding classes of antimicrobials, as multiple mechanisms of antimicrobial resistance exist.

Antimicrobial resistance can occur via multiple mechanisms. A “Not Detected” result for a genetic marker of antimicrobial resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A “Detected” result for a genetic marker of antimicrobial resistance cannot be definitively linked to the microorganism(s) detected. Culture is required to obtain isolates for antimicrobial susceptibility testing, and BIOFIRE Pneumonia Panel *plus* results should be used in conjunction with culture results for determination of bacterial susceptibility or resistance.

Due to the genetic similarity between human rhinovirus and enterovirus, the test cannot reliably differentiate them. A positive Rhinovirus/Enterovirus result should be followed up using an alternate method (e.g., cell culture or sequence analysis) if differentiation is required.

Culture is required to identify pathogens not detected by the BIOFIRE Pneumonia Panel *plus*, to further speciate analytes in genus, complex, or group results if desired, to identify bacterial pathogens present below the 10^4 copies/mL bin if desired, and for antimicrobial susceptibility testing.

Device Description:
The FilmArray Pneumonia Panel *plus* is designed to simultaneously identify MERS-CoV and 26 potential pathogens of lower respiratory tract infection (LRTI) and associated antimicrobial resistance (AMR) genes from a sputum-like (induced and expectorated sputum as well as endotracheal aspirate, ETA) or bronchoalveolar lavage (BAL)-like (BAL and mini-BAL) specimens obtained from individuals meeting MERS-CoV clinical and/or epidemiological criteria in a time (~1 hour). The FilmArray Pneumonia Panel *plus* is compatible with BioFire Diagnostics’ (BioFire) PCR-based in vitro diagnostic BioFire FilmArray 2.0 (K143178) and BioFire FilmArray Torch (K160068) systems for infectious disease testing. A specific software module (i.e., FilmArray Pneumonia Panel *plus* pouch module) is used to perform FilmArray Pneumonia Panel *plus* testing on these systems.

A test is initiated by loading Hydration Solution into one port of the FilmArray pouch and a sputum-like or BAL-like sample mixed with the provided Sample Buffer into the other port of the FilmArray Pneumonia Panel *plus* pouch and placing it in a FilmArray instrument. The pouch contains all the reagents required for specimen testing and analysis in a freeze-dried format; the addition of Hydration Solution and Sample/Buffer Mix rehydrates the reagents. After the pouch is prepared,

the FilmArray Software guides the user though the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, and initiating the run.

The FilmArray instrument contains 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 Diagnostics). 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 end 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 2nd stage PCR 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:

Table 1 outlines the similarities and differences between the two panels.

Table 1 Comparison of the FilmArray Pneumonia Panel *plus* with modified labeling to the current FilmArray Pneumonia Panel *plus*.

Element	Modified Device: FilmArray Pneumonia Panel *plus* (with modified labeling)	Predicate: FilmArray Pneumonia Panel *plus* (K181324)
Organisms Detected	Bacteria: *Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter aerogenes, Enterobacter cloacae* complex, *Escherichia coli*, *Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae* group*, Moraxella catarrhalis, Proteus* spp., *Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes* Atypical Bacteria: *Chlamydia pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae* Antimicrobial Resistance Genes: CTX-M, IMP, KPC, *mecA/C* + MREJ, NDM, Oxa48-like, VIM Viruses: **Middle East Respiratory Syndrome Coronavirus**, Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Parainfluenza virus, Respiratory Syncytial virus	Same
Analyte	DNA/RNA	Same
Specimen Types	Positive blood culture samples containing gram-positive or gram-negative bacteria and/or yeast.	Same
Technological Principles	Nested multiplex PCR followed by high resolution melting analysis to confirm the identity of amplified product.	Same
Instrumentation	Single instrument FilmArray 2.0 System, or FilmArray Torch System	Same
Time to result	About 1 hour	Same
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	Same
Sample Preparation Method	Sample Processing is automated in the BioFire FilmArray PN pouch.	Same
Reagent Storage	Reagents are stored at room temperature.	Same
Shelf-Life	12 months from Date of Manufacture (DOM)*	Same

Element	Modified Device: FilmArray Pneumonia Panel *plus* (with modified labeling)	Predicate: FilmArray Pneumonia Panel *plus* (K181324)
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/High	Same

* LoD for adenovirus species C is 10 – 100 x impaired when pouches are within 6 months of expiration

The purpose of this submission is to modify the labeling of the FilmArray Pneumonia Panel *plus* to include the following limitations in the instructions for use:

> 22. There is an increased risk of false negative Adenovirus results for adenovirus species C when using a pouch that is within 6 months of the expiration date due to a 10-100 x loss in sensitivity (i.e. impairment leading to an increase in the LoD). The test performance is not impacted if kits are more than 6 months from expiration date. Performance for other adenovirus species is not impacted.
>
> 23. If using a pouch that is within 6 months of expiration when a patient is suspected of adenovirus C infection, confirm all negative Adenovirus results using another method prior to reporting the result, or alternatively, do not report a negative Adenovirus result.

An additional footnote in the Analytical LoD section (Table 63) of the Pneumonia Panel *plus* instructions for use will also be included.

Conclusion:
The fundamental scientific technology, performance, and risk of the FilmArray Pneumonia Panel *plus* is unchanged from the legally marketed FilmArray Pneumonia Panel *plus*. There is no change to the product itself, only to the labeling (instructions for use). Therefore, the modified FilmArray Pneumonia Panel *plus* performs as well as the predicate device.