



September 22, 2026

Biofire Diagnostics
Daisy Ramos
Regulatory Affairs Specialist
515 Colorow Dr.
Salt Lake City, Utah 84108

Re: K263054

Trade/Device Name: BIOFIRE Respiratory Panel 2.1 (RP2.1)

Regulation Number: 21 CFR 866.3981

Regulation Name: Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test

Regulatory Class: Class II

Product Code: QOF

Dated: August 31, 2026

Received: September 1, 2026

Dear Daisy Ramos:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,


JOSEPH BRIGGS -S

Joseph Briggs, Ph.D.
Deputy Division Director
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

510(k) Number (if known)

K263054

Device Name

BIOFIRE Respiratory Panel 2.1 (RP2.1)

Indications for Use (Describe)

The BIOFIRE Respiratory Panel 2.1 (RP2.1) is a PCR-based multiplexed nucleic acid test intended for use with the BIOFIRE FILMARRAY 2.0 or BIOFIRE FILMARRAY TORCH 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, including COVID-19. The following organism types and subtypes are identified using the BIOFIRE RP2.1:

- Adenovirus
- Coronavirus 229E
- Coronavirus HKU1
- Coronavirus NL63
- Coronavirus OC43
- Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2)
- Human Metapneumovirus
- Human Rhinovirus/Enterovirus
- Influenza A, including subtypes H1, H1-2009, and H3
- Influenza B
- Parainfluenza Virus 1
- Parainfluenza Virus 2
- Parainfluenza Virus 3
- Parainfluenza Virus 4
- Respiratory Syncytial Virus
- Bordetella parapertussis
- Bordetella pertussis
- Chlamydia pneumoniae
- Mycoplasma pneumoniae

Nucleic acids from the respiratory viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection is indicative of the presence of the identified microorganism and 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 patient 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 may not be detected by an NPS specimen. Positive results do not rule out coinfection with other organisms. The agent(s) detected by the BIOFIRE RP2.1 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.

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.

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BIOFIRE® Respiratory Panel 2.1 (RP2.1)

Special 510(k) Summary

BioFire Diagnostics, LLC

Introduction:

The content of this Special 510(k) submission is limited to obtaining FDA clearance for the BIOFIRE Respiratory Panel 2.1 (RP2.1) (DEN200031) with a software update to mitigate a risk of false negative Parainfluenza 3 (PIV3) results.

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:

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

Contact:

Daisy Ramos
Telephone: +1 385-414-4985
Email: Daisy.Ramos@biomerieux.com

Date Submitted: August 31, 2026

Device Name and Classification:

Trade Name: BIOFIRE® Respiratory Panel 2.1 (RP2.1)

Regulation Number: 21 CFR 866.3981

Classification Name: Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test

Predicate Devices:

DEN200031 – BIOFIRE Respiratory Panel 2.1 (RP2.1)

Background:

Post-market monitoring identified a newly observed Parainfluenza Virus 3 (PIV3) sequence variant associated with melting temperature (T_m) values outside the predefined assay interpretation criteria, which could result in false negative test results. The software was updated to expand the applicable PIV3 melt window to include the T_m range of the observed variant. Clinical and analytical study data were reanalyzed using the modified software, demonstrating performance consistent with that of the previously cleared device.

Summary of Changes

Software Update:

bioMérieux has initiated a software (pouch module) update to expand the applicable PIV3 melt window to include the T_m range of the observed variant. The revised T_m range mitigates the risk of false negative results. Reanalysis of the performance data (clinical and non-clinical/analytical studies) with the modified pouch module software showed no difference in performance.

Intended Use:

The BIOFIRE Respiratory Panel 2.1 (RP2.1) is a PCR-based multiplexed nucleic acid test intended for use with the BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH 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, including COVID-19.

The following organism types and subtypes are identified using the BIOFIRE RP2.1:

Viruses	Bacteria
Adenovirus	<i>Bordetella parapertussis</i>
Coronavirus 229E	<i>Bordetella pertussis</i>
Coronavirus HKU1	<i>Chlamydia pneumoniae</i>
Coronavirus NL63	<i>Mycoplasma pneumoniae</i>
Coronavirus OC43	
Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2)	
Human Metapneumovirus	
Human Rhinovirus/Enterovirus	
Influenza A, including subtypes H1, H1-2009, and H3	
Influenza B	
Parainfluenza Virus 1	
Parainfluenza Virus 2	
Parainfluenza Virus 3	
Parainfluenza Virus 4	
Respiratory Syncytial Virus	

Nucleic acids from the respiratory viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection is indicative of the presence of the identified microorganism and 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 patient 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 may not be detected by an NPS specimen. Positive results do not rule out coinfection with other organisms. The agent(s) detected by the BIOFIRE RP2.1 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.

Device Description:

The BIOFIRE Respiratory Panel 2.1 (RP2.1) is designed to simultaneously identify 22 different potential pathogens of respiratory tract infection, including the novel coronavirus Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), from a single NPS specimen in transport medium, in a timeframe (about 45 minutes) that allows the test results to be used in determining appropriate patient treatment and management.

The BIOFIRE RP2.1 is compatible with BioFire's PCR-based in vitro diagnostic BIOFIRE FILMARRAY 2.0 and BIOFIRE FILMARRAY TORCH systems for infectious disease testing. A specific software module (i.e., BIOFIRE RP2.1 pouch module) is used to perform BIOFIRE RP2.1 testing on these systems.

The BIOFIRE RP2.1 pouch contains the exact same sample preparation and PCR reaction chemistry as the previously cleared BIOFIRE FILMARRAY Respiratory Panel 2 (RP2) (K170604), with the addition of SARS-CoV-2 primers. In addition, the instrument protocol and the analysis parameters in the panel-specific pouch module are the same as for BIOFIRE RP2, with the additional analysis of the SARS-CoV-2 assays.

A test is initiated by loading Hydration Solution into one port of the reagent pouch and NPS specimen mixed with the provided Sample Buffer into the other port of the BIOFIRE RP2.1 pouch, then placing the pouch into a BIOFIRE System. The pouch contains all of the reagents required for specimen testing and analysis in a freeze-dried format; the addition of Hydration Solution and the Sample/Buffer mixture rehydrates the reagents. After the pouch is prepared, the BIOFIRE 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.

The BIOFIRE system modules contain coordinated systems 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 reagent 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 BioFire instrument module performs a nested multiplex PCR that is executed in two stages. During the first stage, the instrument module 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 (LCGreen® *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 second-stage PCR, or nested PCR, is performed in singleplex fashion in each well of the array. At the conclusion of the second-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 second-stage PCR captures fluorescent images of the PCR reactions, and software interprets the data.

The BIOFIRE 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 modified BIOFIRE RP2.1 and the predicate panel.

Table 1. Comparison of the BIOFIRE RP2.1 and the BIOFIRE RP2.1 with Software Update

Element	Predicate: BIOFIRE RP2.1 (DEN200031)	Current BIOFIRE RP2.1 with software update																																
Intended Use	The BIOFIRE Respiratory Panel 2.1 (RP2.1) is a PCR-based multiplexed nucleic acid test intended for use with the BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH 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, including COVID-19. The following organism types and subtypes are identified using the BIOFIRE RP2.1: <table><thead><tr><th>Viruses</th><th>Bacteria</th></tr></thead><tbody><tr><td>Adenovirus</td><td><i>Bordetella parapertussis</i></td></tr><tr><td>Coronavirus 229E</td><td><i>Bordetella pertussis</i></td></tr><tr><td>Coronavirus HKU1</td><td><i>Chlamydia pneumoniae</i></td></tr><tr><td>Coronavirus NL63</td><td><i>Mycoplasma pneumoniae</i></td></tr><tr><td>Coronavirus OC43</td><td></td></tr><tr><td>Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2)</td><td></td></tr><tr><td>Human Metapneumovirus</td><td></td></tr><tr><td>Human Rhinovirus/Enterovirus</td><td></td></tr><tr><td>Influenza A, including subtypes H1, H1-2009, and H3</td><td></td></tr><tr><td>Influenza B</td><td></td></tr><tr><td>Parainfluenza Virus 1</td><td></td></tr><tr><td>Parainfluenza Virus 2</td><td></td></tr><tr><td>Parainfluenza Virus 3</td><td></td></tr><tr><td>Parainfluenza Virus 4</td><td></td></tr><tr><td>Respiratory Syncytial Virus</td><td></td></tr></tbody></table> Nucleic acids from the respiratory viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection is indicative of the presence of the identified microorganism and 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 patient 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 may not be detected by an NPS specimen. Positive results do not rule out coinfection with other organisms. The agent(s) detected by the BIOFIRE RP2.1 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.	Viruses	Bacteria	Adenovirus	<i>Bordetella parapertussis</i>	Coronavirus 229E	<i>Bordetella pertussis</i>	Coronavirus HKU1	<i>Chlamydia pneumoniae</i>	Coronavirus NL63	<i>Mycoplasma pneumoniae</i>	Coronavirus OC43		Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2)		Human Metapneumovirus		Human Rhinovirus/Enterovirus		Influenza A, including subtypes H1, H1-2009, and H3		Influenza B		Parainfluenza Virus 1		Parainfluenza Virus 2		Parainfluenza Virus 3		Parainfluenza Virus 4		Respiratory Syncytial Virus		Same
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Specimen Type	Nasopharyngeal Swab (NPS) in transport media or normal saline	Same																																
Analyte	DNA/RNA	Same																																
Technological Principles	Highly-multiplexed nested nucleic acid amplification test with melt analysis	Same																																
Instrumentation	BIOFIRE FILMARRAY 2.0 or BIOFIRE FILMARRAY TORCH	Same																																
Time to result	About 45 min	Same																																
Reagent Storage	Room temperature	Same																																
Sample Preparation Method	Sample Processing is automated in the BIOFIRE System.	Same																																
Shelf-Life	18 months from Date of Manufacture	Same																																
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	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	Same																																

Conclusion:

The software modification does not affect the fundamental scientific technology, overall performance claims, or risk of the BIOFIRE RP2.1. Therefore, the modified BIOFIRE RP2.1 performs as well as the predicate device.