April 13, 2023

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

Re: K230719
Trade/Device Name: BIOFIRE SPOTFIRE Respiratory (R) Panel Mini
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, OCC, OTG, OZE
Dated: March 15, 2023
Received: March 15, 2023

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,

Joseph Briggs -S

Joseph Briggs, Ph.D.
Deputy Branch Chief
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)*
K230719

Device Name
BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini

Indications for Use *(Describe)*
The BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini (SPOTFIRE R Panel Mini) is a multiplexed polymerase chain reaction (PCR) test intended for use with the BIOFIRE® SPOTFIRE® System for the simultaneous, qualitative detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swab (NPS) specimens obtained from individuals with signs and symptoms of respiratory tract infection, including COVID-19.

The following organism types and subtypes are identified and differentiated using the SPOTFIRE R Panel Mini:

- Coronavirus SARS-CoV-2
- Human rhinovirus
- Influenza A virus
- Influenza B virus
- Respiratory syncytial virus

Nucleic acids from the viral organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection are indicative of the presence of the identified microorganism and aids in diagnosis if used in conjunction with other clinical and epidemiological information, and laboratory findings. 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 SPOTFIRE R Panel Mini 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.

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."

BIOFIRE® SPOTFIRE® Respiratory Panel Mini

Special 510(k) Summary
BioFire Diagnostics, LLC

Introduction:

The purpose of this Special 510(k) submission is to obtain clearance for the BIOFIRE SPOTFIRE Respiratory (R) Panel Mini.

The SPOTFIRE R Panel Mini is an identical product to the BIOFIRE SPOTFIRE Respiratory (R) Panel (K213954) that uses modified labeling and modified software to report five of the 15 analytes available on the SPOTFIRE R Panel (see Table 1).

Additionally, the modified software collapses the result of Influenza A into a single call (reported as Influenza A Subtype H3 or Influenza A Subtype H1-2009 on the SPOTFIRE R Panel).

Modifications to the BIOFIRE R Panel labeling, which includes changes to the *Instructions for Use* and *Quick Guide,* have been made to reflect the change in panel name and reported analytes.

According to the requirements of 21 CFR 807.92, the information included with this submission provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by:

BioFire Diagnostics, LLC
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: March 15, 2023

Device Name and Classification:

Trade name: BIOFIRE® SPOTFIRE® Respiratory Panel Mini

Regulation Number: 21 CFR 866.3981

Classification Name: Multi-Target Respiratory Specimen Nucleic Acid Test Including Sars-Cov-2 And Other Microbial Agents

Predicate Device:

K213954 – BIOFIRE® SPOTFIRE® Respiratory (R) Panel

Intended Use:

The BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini (SPOTFIRE R Panel Mini) is a multiplexed polymerase chain reaction (PCR) test intended for use with the BIOFIRE® SPOTFIRE® System for the simultaneous, qualitative detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swab (NPS) specimens obtained from individuals with signs and symptoms of respiratory tract infection, including COVID-19.

The following organism types and subtypes are identified and differentiated using the SPOTFIRE R Panel Mini:

- Coronavirus SARS-CoV-2
- Human rhinovirus
- Influenza A virus
- Influenza B virus
- Respiratory syncytial virus

Nucleic acids from the viral organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection are indicative of the presence of the identified microorganism and aids in diagnosis if used in conjunction with other clinical and epidemiological information, and laboratory findings. 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 SPOTFIRE R Panel Mini 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 SPOTFIRE Respiratory (R) Panel Mini simultaneously identifies five different respiratory viral pathogens in nasopharyngeal swabs (NPS) from individuals with signs and symptoms of respiratory tract infection (see Table 1). The SPOTFIRE R Panel Mini is compatible with the BIOFIRE® SPOTFIRE® System, a polymerase chain reaction (PCR)-based in vitro diagnostic system for infectious disease testing. The BIOFIRE SPOTFIRE System Software executes the SPOTFIRE R Panel Mini test and interprets and reports the test results.

Table 1. Analytes Detected by the SPOTFIRE R Panel Mini

Viruses
Coronavirus SARS-CoV-2
Human rhinovirus
Influenza A virus
Influenza B virus
Respiratory syncytial Virus

A test is initiated by loading Hydration Solution into one port of the SPOTFIRE R Panel Mini pouch and NPS specimen mixed with the provided Sample Buffer into the other port of the SPOTFIRE R Panel Mini pouch and placing it in the SPOTFIRE 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 Sample/Buffer Mix rehydrates the reagents. After the pouch is prepared, the SPOTFIRE System 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 SPOTFIRE System contains 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 SPOTFIRE R Panel Mini 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 SPOTFIRE System performs a nested multiplex PCR that is executed in two stages. During the first stage, the SPOTFIRE System 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 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 2nd stage PCR captures fluorescent images of the PCR reactions and software interprets the data.

The SPOTFIRE System 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.

Substantial Equivalence:

The SPOTFIRE R Panel Mini is substantially equivalent to the SPOTFIRE R Panel (K213954), which was cleared on February 03, 2023, and determined to be a Class II device under the classification code 21 CFR 866.3981.

A table comparing the SPOTFIRE R Panel Mini to the SPOTFIRE R Panel is provided in Table 2.

Table 2. Similarities and differences between the SPOTFIRE R Panel and the SPOTFIRE R Panel Mini

Element	Predicate: SPOTFIRE R Panel (K213954)	New Device: SPOTFIRE R Panel Mini
Intended Use	The BIOFIRE® SPOTFIRE® Respiratory (R) Panel (SPOTFIRE R Panel) is a multiplexed polymerase chain reaction (PCR) test intended for use with the BIOFIRE® SPOTFIRE® System for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab (NPS) specimens obtained from individuals with signs and symptoms of respiratory tract infection, including COVID-19. The following organism types and subtypes are identified and differentiated using the SPOTFIRE R Panel: <u>Viruses</u> Adenovirus Coronavirus (seasonal) Coronavirus SARS-CoV-2 Human metapneumovirus Human rhinovirus/enterovirus Influenza A virus Influenza A virus A/H1-2009 Influenza A virus A/H3 Influenza B virus Parainfluenza virus Respiratory syncytial virus <u>Bacteria</u> *Bordetella parapertussis* *Bordetella pertussis* *Chlamydia pneumoniae* *Mycoplasma pneumoniae* Nucleic acids from the viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and	The BIOFIRE® SPOTFIRE® Respiratory ® Panel Mini (SPOTFIRE R Panel Mini) is a multiplexed polymerase chain reaction (PCR) test intended for use with the BIOFIRE® SPOTFIRE® System for the simultaneous, qualitative detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swab (NPS) specimens obtained from individuals with signs and symptoms of respiratory tract infection, including COVID-19. The following organism types are identified and differentiated using the SPOTFIRE R Panel Mini: • Coronavirus SARS-CoV-2 • Human rhinovirus • Influenza A virus • Influenza B virus • Respiratory syncytial virus Nucleic acids from the viral organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection are indicative of the presence of the identified microorganism and aids in diagnosis if used in conjunction with other clinical and epidemiological information, and laboratory findings. 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

	identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection are indicative of the presence of the identified microorganism and aids in diagnosis if used in conjunction with other clinical and epidemiological information, and laboratory findings. 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 SPOTFIRE R Panel 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.	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 SPOTFIRE R Panel Mini 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.
Specimen Types	Nasopharyngeal swab in transport media	Same
Organisms detected	**<u>Viruses</u>** Adenovirus Coronavirus (seasonal) Coronavirus SARS-CoV-2 Human metapneumovirus Human rhinovirus/enterovirus Influenza A virus Influenza A virus A/H1-2009 Influenza A virus A/H3 Influenza B virus Parainfluenza virus Respiratory syncytial virus **Bacteria** *Chlamydia pneumoniae* *Mycoplasma pneumoniae* *Bordetella parapertussis* *Bordetella pertussis*	**<u>Viruses</u>** Coronavirus SARS-CoV-2 Human rhinovirus Influenza A virus Influenza B virus Respiratory syncytial virus
Analytes	DNA/RNA	RNA
Technological Principles	Highly multiplexed nested nucleic acid amplification test with melt analysis	Same
Instrumentation	SPOTFIRE System	Same
Time to result	About 15 minutes	Same
Reagent Storage	Room Temperature	Same
Test Interpretation	Automated test interpretation and reporting. 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	Low (CLIA-waived)	Same
Panel Software Functions	Defines panel-specific parameters, instrument protocols and report requirements.	Same
	Analyzes processed image data (fluorescence and temperature data) and provides test results.	Same

Summary of Performance Data:

The performance data for the SPOTFIRE R Panel Mini is identical to the SPOTFIRE R Panel (K213954), but only contains data for the five analytes detected by the SPOTFIRE R Panel Mini (Coronavirus SARS-CoV-2, human rhinovirus, influenza A virus, influenza B virus, and respiratory syncytial virus). Please see the *BIOFIRE SPOTFIRE Respiratory Panel Mini Instructions for Use* for performance tables.

Conclusion:

The fundamental scientific technology, performance, and risk of the SPOTFIRE R Panel Mini is unchanged from the legally marketed SPOTFIRE R Panel. There is no change to the product itself, except for modified software that has been verified and validated to show no change in safety and effectiveness. Therefore, the SPOTFIRE R Panel Mini performs as well as the predicate device.