December 5, 2024

BioFire Diagnostics, LLC (bioMerieux)
Karli Plenert
Sr Director, Regulatory Affairs
515 Colorow Drive
Salt Lake City, Utah 84108

Re: K243463
Trade/Device Name: BIOFIRE FILMARRAY Tropical Fever Panel
Regulation Number: 21 CFR 866.3966
Regulation Name: Device To Detect And Identify Selected Microbial Agents That Cause Acute Febrile Illness
Regulatory Class: Class II
Product Code: QMV
Dated: November 7, 2024
Received: November 8, 2024

Dear Karli Plenert:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Bryan M. Grabias -S

Digitally signed by Bryan M. Grabias -S
Date: 2024.12.05 14:24:06 -05'00'

Bryan Grabias
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243463

Device Name
BIOFIRE FILMARRAY Tropical Fever Panel

Indications for Use *(Describe)*
The BIOFIRE FILMARRAY Tropical Fever (TF) Panel is an automated qualitative, multiplexed, polymerase chain reaction (PCR) test intended for use with BIOFIRE FILMARRAY 2.0 and BIOFIRE FILMARRAY TORCH Systems. The BIOFIRE FILMARRAY TF Panel detects and identifies selected bacterial, viral, and parasitic nucleic acids directly from EDTA whole blood collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4), Leptospira spp., and Plasmodium spp. (including species differentiation of Plasmodium falciparum and Plasmodium vivax/ovale).

Evaluation for more common causes of acute febrile illness (e.g., infections of the upper and lower respiratory tract or gastroenteritis, as well as non-infectious causes) should be considered prior to evaluation with this panel. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data, in accordance with the guidelines provided by the relevant public health authorities.

The BIOFIRE FILMARRAY TF Panel is not intended to be used as the sole basis for diagnosis, treatment, or other management decisions. Positive results do not rule out co-infection with other organisms not included on the BIOFIRE FILMARRAY TF Panel, nor do negative results rule out infection. Negative results from the BIOFIRE FILMARRAY TF Panel may require additional testing if clinically indicated. Not all pathogens that cause acute febrile illness are detected by this test, and negative results do not rule out the presence of other infections.

In the United States, patient travel history, exposure risk, and consultation of the CDC Yellow Book should be considered prior to use of the BIOFIRE FILMARRAY TF Panel as some pathogens are more common in certain geographical locations.

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.

BIOFIRE® FILMARRAY® Tropical Fever Panel

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® FILMARRAY® Tropical Fever (TF) Panel, a rebranded version of the BioFire Global Fever Panel (K220870). 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:
Karli Plenert, MBA
Telephone: +1 385-414-4985
Email: Karli.Plenert@biomerieux.com

Date Submitted: November 07, 2024

Device Name and Classification:

Trade Name: BIOFIRE FILMARRAY Tropical Fever (TF) Panel

Regulation Number: 21 CFR 866.3966

Classification Name: Device To Detect And Identify Selected Microbial Agents That Cause Acute Febrile Illness

Predicate Devices:

K220870 – BioFire Global Fever Panel

Background:

The BioFire Global Fever Panel (K220870) is designed, developed, and currently manufactured by BioFire Defense, LLC (a wholly owned subsidiary of bioMérieux, Inc.). The BIOFIRE FILMARRAY Tropical Fever (TF) Panel is a rebranded version of the BioFire Global Fever panel that includes updated pouch module software, product labeling, instructions for use, and a new panel name. The performance claims of the BIOFIRE FILMARRAY TF Panel remain identical to the predicate BioFire Global Fever Panel.

BioFire Defense will remain the legal manufacturer of the BioFire Global Fever Panel. BioFire Diagnostics, LLC (also a wholly owned subsidiary of bioMérieux, Inc.) will be the legal manufacturer of the BIOFIRE FILMARRAY TF Panel and BioFire Defense will be the contract manufacturer for the device.

Modifications:

Software Update

The BIOFIRE FILMARRAY TF Panel Pouch Module software has been developed to support the rebranded panel and includes the following changes:

- Change to the panel name,
- Update to report to align the report appearance and layout with other BIOFIRE FILMARRAY IVD panels sold by bioMérieux, and
- Add cross-compatibility with the latest BIOFIRE FILMARRAY Systems Software.

Labeling and Branding Update:

A new BIOFIRE FILMARRAY TF Panel instructions for use has been created to align with bioMérieux branding guidelines for the BIOFIRE product line and reflects the updated panel name. In addition, physical product labeling has been created to include the new product branding and panel name.

Intended Use:

The BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel is an automated, qualitative, multiplexed polymerase chain reaction (PCR) test intended for use with BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® FILMARRAY® TORCH Systems. The BIOFIRE FILMARRAY TF Panel detects and identifies selected bacterial, viral, and parasitic nucleic acids directly from EDTA whole blood collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4), *Leptospira* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*).

Evaluation for more common causes of acute febrile illness (e.g., infections of the upper and lower respiratory tract or gastroenteritis, as well as non-infectious causes) should be considered prior to evaluation with this panel. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data, in accordance with the guidelines provided by the relevant public health authorities.

The BIOFIRE FILMARRAY TF Panel is not intended to be used as the sole basis for diagnosis, treatment, or other management decisions. Positive results do not rule out co-infection with other organisms not included on the BIOFIRE FILMARRAY TF Panel, nor do negative results rule out infection. Negative results from the BIOFIRE FILMARRAY TF Panel may require additional testing if clinically indicated. Not all pathogens that cause acute febrile illness are detected by this test, and negative results do not rule out the presence of other infections.

In the United States, patient travel history, exposure risk, and consultation of the CDC Yellow Book should be considered prior to use of the BIOFIRE FILMARRAY TF Panel as some pathogens are more common in certain geographical locations.

Intended User and Use Environment

The BIOFIRE FILMARRAY TF Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional.

Device Description:

The BIOFIRE FILMARRAY TF Panel is a rebranded version of the BioFire Global Fever Panel. It is designed to simultaneously identify 6 pathogens from whole blood specimens collected in EDTA tubes. The BIOFIRE FILMARRAY TF Panel is compatible with BioFire's PCR-based in vitro diagnostic BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® FILMARRAY® TORCH Systems for infectious disease testing. A panel-specific software module (i.e., BIOFIRE FILMARRAY TF Panel pouch module software) is used to perform BIOFIRE FILMARRAY TF Panel testing on these systems. Results from the BIOFIRE FILMARRAY TF Panel test are available within about one hour.

A test is initiated by loading Hydration Solution into one port of the pouch and a whole blood or positive blood culture specimen mixed with the provided Sample Buffer into the other port of the BIOFIRE FILMARRAY TF Panel pouch and placing it in a BIOFIRE System. 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 BIOFIRE 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 BIOFIRE System 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 BIOFIRE 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 system performs a nested multiplex PCR that is executed in two stages. During the first stage, the BIOFIRE 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. 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 single plex 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 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 BIOFIRE FILMARRAY TF Panel with the BioFire Global Fever Panel.

Table 1. Comparison of the BIOFIRE FILMARRAY TF Panel with the BioFire Global Fever Panel.

Element	Modified Device: BIOFIRE FILMARRAY TF Panel	Predicate: BioFire Global Fever Panel (K220870)
Intended Use	The BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel is an automated, qualitative, multiplexed polymerase chain reaction (PCR) test intended for use with BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® FILMARRAY® TORCH Systems. The BIOFIRE FILMARRAY TF Panel detects and identifies selected bacterial, viral, and parasitic nucleic acids directly from EDTA whole blood collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4), *Leptospira* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*). Evaluation for more common causes of acute febrile illness (e.g., infections of the upper and lower respiratory tract or gastroenteritis, as well as non-infectious causes) should be considered prior to evaluation with this panel. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data, in accordance with the guidelines provided by the relevant public health authorities. The BIOFIRE FILMARRAY TF Panel is not intended to be used as the sole basis for diagnosis, treatment, or other management decisions. Positive results do not rule out co-infection with other organisms not included on the BIOFIRE FILMARRAY TF Panel, nor do negative results rule out infection. Negative results from the BIOFIRE FILMARRAY TF Panel may require additional testing if clinically indicated. Not all pathogens that cause acute febrile illness are detected by this test, and negative results do not rule out the presence of other infections. In the United States, patient travel history, exposure risk, and consultation of the CDC Yellow Book should be considered prior to use of the BIOFIRE FILMARRAY TF Panel as some pathogens are more common in certain geographical locations.	The BioFire® Global Fever Panel is a qualitative, multiplexed, nucleic acid-based in vitro diagnostic test intended for use with BioFire® FilmArray® 2.0 and BioFire® FilmArray® Torch Systems. The BioFire Global Fever Panel detects and identifies selected bacterial, viral, and protozoan nucleic acids directly from EDTA whole blood collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4), *Leptospira* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*). Evaluation for more common causes of acute febrile illness (e.g., infections of the upper and lower respiratory tract or gastroenteritis, as well as non-infectious causes) should be considered prior to evaluation with this panel. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data, in accordance with the guidelines provided by the relevant public health authorities. Positive results do not rule out co-infections with pathogens not included on the BioFire Global Fever Panel. Not all pathogens that cause acute febrile illness are detected by this test, and negative results do not rule out the presence of other infections. In the United States, patient travel history and consultation of the CDC Yellow Book should be considered prior to use of the BioFire Global Fever Panel as some pathogens are more common in certain geographical locations.
Organisms Detected	*Leptospira spp.* Chikungunya virus Dengue virus (serotypes 1, 2, 3 and 4) *Plasmodium spp.* *Plasmodium falciparum* *Plasmodium vivax/ovale*	Same
Analyte	DNA/RNA	Same
Specimen Types	Whole blood (collected in EDTA tube)	Same
Technological Principles	Nested multiplex PCR followed by high resolution melting analysis to confirm the identity of amplified product.	Same
Instrumentation	BIOFIRE 2.0 System or BIOFIRE TORCH System	Same
Time to result	~ 50 minutes	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 System.	Same
Reagent Storage	Reagents are stored at room temperature.	Same
Shelf-Life	12 months from Date of Manufacture.	Same

Element	Modified Device: BIOFIRE FILMARRAY TF Panel	Predicate: BioFire Global Fever Panel (K220870)
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
Legal Manufacturer	*BioFire Diagnostics, LLC.	*BioFire Defense, LLC.

*Note: BioFire Diagnostics, LLC and BioFire Defense, LLC are both wholly owned subsidiaries of bioMérieux, Inc.

Conclusion:

The fundamental scientific technology, performance claims, or risk of the BIOFIRE FILMARRAY TF Panel are unchanged from the legally marketed BioFire Global Fever Panel. There is no change to the product itself, except for updated software that has been verified and validated to show no change in safety and effectiveness, instructions for use, product labeling, and branding. Therefore, the BIOFIRE FILMARRAY TF Panel is substantially equivalent to its predicate device.