July 17, 2026

Biofire Defense, LLC
David Rabiger
Director of Regulatory and Clinical Affairs
79 W 4500 S
Suite 14
Salt Lake City, Utah 84107

Re: K261475
Trade/Device Name: BIOFIRE FILMARRAY Tropical Fever Panel Control Kit
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed quality control material for clinical microbiology assays
Regulatory Class: Class II
Product Code: PMN
Dated: May 4, 2026
Received: May 5, 2026

Dear David Rabiger:

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 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,

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Bryan Grabias, Ph.D.
Acting Branch Chief
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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)*
K261475

Device Name
BIOFIRE FILMARRAY Tropical Fever Panel Control Kit

Indications for Use *(Describe)*
The BIOFIRE FILMARRAY Tropical Fever Panel Control Kit contains Positive and Negative External Controls intended for use as assayed quality controls to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of 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) when using the BIOFIRE FILMARRAY Tropical Fever Panel on the BIOFIRE FILMARRAY 2.0 and BIOFIRE FILMARRAY TORCH Systems. The BIOFIRE FILMARRAY Tropical Fever Panel Control Kit is designed for and intended to be used solely with the BIOFIRE FILMARRAY Tropical Fever Panel. This product does not replace manufacturer internal controls provided as part of the BIOFIRE FILMARRAY Tropical Fever Panel.

Both the Positive and Negative External Controls are provided in a Control Injection Vial format. The Positive Control Injection Vial contains dried synthetic nucleic acid segments in buffer and stabilizer to assess for the presence of each individual assay on the BIOFIRE FILMARRAY Tropical Fever Panel. The Negative Control Injection Vial is non-reactive with the BIOFIRE FILMARRAY Tropical Fever Panel.

For In Vitro Diagnostic Use.

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.**

# 510(k) Summary

## I. Submitter

BioFire Defense, LLC
79 West 4500 South, Suite 14
Salt Lake City, UT 84107
**Phone:** (801) 262-3592
**Fax:** (801) 447-6907
**Contact Person:** David Rabiger, PhD
**Date Prepared:** May 4, 2026

## II. Device

**Trade Name:** BIOFIRE® FILMARRAY® Tropical Fever Panel Control Kit
**Common or Usual Name:** BIOFIRE TF Panel Control Kit
**Regulation:** 21 CFR 866.3920
**Classification Name:** Assayed external control material for microbiology nucleic acid amplification (NAT) assays
**Product Code:** PMN
**Regulatory Class:** Class II (Special Controls)
**Panel:** Microbiology – 83

## III. Predicate Device

BIOFIRE® SHIELD™ Control Kit for the BioFire Global Fever Panel [K220870]
This predicate device has not been subject to a design-related recall.

## IV. Device Description

The BIOFIRE FILMARRAY Tropical Fever (BIOFIRE TF) Panel Control Kit is an assayed external quality control intended for monitoring the diagnostic performance of the BIOFIRE® FILMARRAY® Tropical Fever (BIOFIRE TF) Panel. The BIOFIRE TF Panel Control Kit consists of Positive and Negative Controls in a single-use Control Injection Vial format. The Positive External Controls contain synthetic nucleic acid segments in buffer and stabilizer embedded on the filter of a Control Injection Vial. The nucleic acid segments are designed to be detected by each of the assays on the BIOFIRE TF Panel and are 100% non-infectious. The Negative External Controls contain no nucleic acid and are non-reactive with the BIOFIRE TF Panel. Vials of Surrogate Sample are provided in the kit which are used in place of a clinical specimen when running the Positive and Negative External Controls.

An external control test is initiated by loading Hydration Solution into one port of the BIOFIRE TF Panel pouch. Surrogate Sample is mixed with Sample Buffer in a Control Injection Vial and inserted into the

other port of the pouch. After the pouch is prepared, the existing BIOFIRE TF Panel software guides the user through the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, selecting the appropriate protocol, and initiating the run on one of the BIOFIRE Systems (2.0 or TORCH). A successful Positive External Control run is indicated by all BIOFIRE TF Panel assays being reported as 'Detected'. A successful Negative External Control run will report all results for the BIOFIRE TF Panel assays as 'Not Detected'.

## V. Intended Use

The BIOFIRE® FILMARRAY® Tropical Fever Panel Control Kit contains Positive and Negative External Controls intended for use as assayed quality controls to monitor the performance of *in vitro* diagnostic laboratory nucleic acid testing procedures for the qualitative detection of 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*) when using the BIOFIRE® FILMARRAY® Tropical Fever Panel on the BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® FILMARRAY® TORCH Systems. The BIOFIRE® FILMARRAY® Tropical Fever Panel Control Kit is designed for and intended to be used solely with the BIOFIRE® FILMARRAY® Tropical Fever Panel. This product does not replace manufacturer internal controls provided as part of the BIOFIRE® FILMARRAY® Tropical Fever Panel.

Both the Positive and Negative External Controls are provided in a Control Injection Vial format. The Positive Control Injection Vial contains dried synthetic nucleic acid segments in buffer and stabilizer to assess for the presence of each individual assay on the BIOFIRE® FILMARRAY® Tropical Fever Panel. The Negative Control Injection Vial is non-reactive with the BIOFIRE® FILMARRAY® Tropical Fever Panel.

**For In Vitro Diagnostic Use.**

## VI. Substantial Equivalence

The BIOFIRE TF Panel Control Kit is substantially equivalent to the BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel. The BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel was cleared on October 20, 2022 (K220870).

The BIOFIRE TF Panel Control Kit is substantially equivalent to the BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel in that they both are external assayed quality controls intended to monitor diagnostic laboratory procedure. Both controls are provided in the same format, run on the same instrumentation, target the same assays, and operate with similar technological principles. While there are differences between these products regarding the compatible panel, both products are intended to be used with the BIOFIRE FILMARRAY platform and have similar technological principles.

**Table 1. Comparison of the BIOFIRE FILMARRAY Tropical Fever Panel Control Kit and Predicate Device**

| Element | Subject Device: BIOFIRE TF Panel Control Kit | Predicate Device: BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel |
|---|---|---|
| **Intended Use** | External assayed quality controls to monitor the performance of *in vitro* diagnostic laboratory nucleic acid testing procedure for the qualitative detection of pathogens detected by the BIOFIRE TF Panel:<br>• Chikungunya virus<br>• Dengue virus (serotypes 1, 2, 3, and 4)<br>• *Leptospira* spp.<br>• *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*) | External assayed quality controls to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of pathogens detected by the BioFire Global Fever Panel:<br>• Chikungunya virus<br>• Dengue virus (serotypes 1, 2, 3, and 4)<br>• *Leptospira* spp.<br>• *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*) |
| **Physical Format** | Control Injection Vial | Same |
| **Controls Included** | Six (6) Positive Controls and six (6) Negative Controls | Same |
| **Composition** | Synthetic RNA templates (positive control only) in buffer and stabilizer | Synthetic DNA segments (positive control only) in buffer and stabilizer |
| **Assay Steps Monitored** | Reverse transcription, amplification, detection, identification | Same except reverse transcription |
| **Reagent Storage** | Room temperature | Same |
| **Test System** | BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH Systems | Same |

# VII. Summary of Performance Data

A multi-site reproducibility precision study was conducted to assess the performance of the BIOFIRE TF Panel Control Kit. This study interrogated the performance of the BIOFIRE TF Panel Control Kit in the context of multiple variables such as panel and control kit lots, BIOFIRE Systems, operators, and test locations.

**DF-SDY-034186 *BIOFIRE Tropical Fever Panel Control Kit Reproducibility***

The goal of this study was to demonstrate reproducible test results for the BIOFIRE TF Panel Control Kit Positive and Negative Controls when used in the context of multiple variables such as different control kit lots, BIOFIRE TF Panel kit lots, BIOFIRE 2.0 or TORCH instruments, operators, and test locations.

Control Kit lots from three different manufacturing events were evaluated at three test sites by two operators using three different BIOFIRE TF Panel kit lots on BIOFIRE FILMARRAY 2.0 and BIOFIRE FILMARRAY TORCH instruments. Testing took place over five non-consecutive days at each site. Reproducibility was evaluated by comparing the observed results to the expected results (Passed) for each

control type. The percent agreement between the observed and expected test results for the Positive and Negative Controls per test site, instrument, and overall are shown in **Table 2**.

**Table 2. Multi-Site Reproducibility Test Results of the BIOFIRE Tropical Fever Panel Control Kit**

| Control Type | Observed/Expected (Percent Agreement) [95% Confidence Interval] | | | |
|---|---|---|---|---|
| | Site 1 | Site 2 | Site 3 | All Sites |
| **Positive** | 90/90 (100%) [95.9 - 100.0] | 89/90 (98.9%) [94.0 - 99.8] | 89/90 (98.9%) [94.0 - 99.8] | 268/270 (99.3%) [97.3 - 99.8] |
| **Negative** | 90/90 (100%) [95.9 - 100.0] | 89/90 (98.9%) [94.0 - 99.8] | 90/90 (100%) [95.9 - 100.0] | 269/270 (99.6%) [97.9 - 99.9] |
| **Overall Agreement with Expected Result** | | | | **537/540 (99.4%) [98.4 - 99.8]** |

The expected result was observed in 99.3% of Positive Control runs and 99.6% of Negative Control runs. Overall agreement with the expected results was 99.4% for the BIOFIRE TF Panel Control Kit.

### Conclusions of BIOFIRE TF Panel Control Kit Performance Testing

The performance data included with this submission demonstrates that the BIOFIRE TF Panel Control Kit returns highly reproducible and accurate results across multiple sites as an assayed external quality control.

Overall, these data support a substantial equivalence decision for the BIOFIRE TF Panel Control Kit.