



November 20, 2020

BioFire Defense, LLC
Cynthia Phillips
VP of Regulatory, Quality, and Clinical Affairs
79 West 4500 South
Suite 14
Salt Lake City, Utah 84107

Re: DEN200043

Trade/Device Name: FilmArray Global 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: June 24, 2020

Received: June 26, 2020

Dear Cynthia Phillips:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the FilmArray Global Fever Panel, a prescription device with the following indications for use:

The FilmArray Global Fever Panel is a qualitative, multiplexed, nucleic acid-based in vitro diagnostic test intended for use with the FilmArray 2.0 system. The FilmArray 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: *Leptospira* spp., chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4), 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 FilmArray 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. Patient travel history and consultation of the CDC Yellow Book should be considered prior to use of the FilmArray Global Fever Panel as some pathogens are more common in certain geographical locations.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the FilmArray Global Fever Panel, and substantially equivalent devices of this generic type, into Class II under the generic name Device to detect and identify selected microbial agents in human clinical specimens that cause acute febrile illness.

FDA identifies this generic type of device as:

A device to detect and identify selected microbial agents that cause acute febrile illness. A device to detect and identify selected microbial agents that cause acute febrile illness is identified as a in vitro device intended for the detection and identification of microbial agents in human clinical specimens from patients with signs and symptoms of acute febrile illness who are at risk for exposure or who may have been exposed to these agents. It is intended to aid in the diagnosis of acute febrile illness in conjunction with other clinical, epidemiologic, and laboratory data, including patient travel, pathogen endemicity, or other risk factors.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On June 26, 2020, FDA received your De Novo requesting classification of the FilmArray Global Fever Panel. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the FilmArray Global Fever Panel into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the FilmArray Global Fever Panel can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Risk of an inaccurate test result (false positive or false negative result) leading to improper patient management	Certain labeling information, including certain limiting statements and performance information. Certain design verification and validation, including certain analytical studies and clinical studies. Use of certain specimen collection devices.
Misinterpretation of test results leading to misdiagnosis and associated risk of false test results	Certain labeling information, including certain limiting statements and performance information. Certain design verification and validation, including certain analytical studies and clinical studies.
Failure to correctly operate the device leading to inaccurate test results	Certain labeling information, including certain limiting statements and performance information. Certain design verification and validation, including certain analytical studies and clinical studies. Use of certain specimen collection devices.

In combination with the general controls of the FD&C Act, a device to detect and identify selected microbial agents that cause acute febrile illness is subject to the following special controls:

1. Any sample collection device used must be FDA-cleared, -approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of specimen types claimed by this device; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device.
2. The labeling required under 21 CFR 809.10(b) must include:
 - i. An intended use that includes a detailed description of targets the device detects and measures, the results provided to the user, the clinical indications appropriate for test use, and the specific population(s) for which the device is intended.
 - ii. Limiting statements indicating:
 - (A) Not all pathogens that cause febrile illness are detected by this test and negative results do not rule out the presence of other infections;
 - (B) Evaluation of more common causes of acute febrile illness should be considered prior to evaluation with this test;
 - (C) Test results are to be interpreted in conjunction with other clinical, epidemiologic, and laboratory data available to the clinician; and

- (D) When using this test, consider patient travel history and exposure risk, as some pathogens are more common in certain geographical locations.
 - iii. A detailed device description, including reagents, instruments, ancillary materials, all control elements, and a detailed explanation of the methodology, including all pre-analytical methods for processing of specimens.
 - iv. Detailed discussion of the performance characteristics of the device for all claimed specimen types as shown by the analytical and clinical studies required under paragraphs (3)(ii) and (3)(iii) of this section, except specimen stability performance characteristics.
 - v. A statement that nationally notifiable results are to be reported to public health authorities in accordance with local, state, and federal law.
3. Design verification and validation must include:
- i. A detailed device description (e.g., all device parts, control elements incorporated into the test procedure, reagents required but not provided, the principle of device operation and test methodology), and the computational path from collected raw data to reported result (e.g., how collected raw signals are converted into a reported result).
 - ii. Detailed documentation of analytical studies, including those demonstrating Limit of Detection (LoD), inclusivity, cross-reactivity, microbial interference, interfering substances, competitive inhibition, carryover/cross contamination, specimen stability, within lab precision, and reproducibility, as appropriate.
 - iii. Detailed documentation and performance results from a clinical study that includes prospective (sequentially collected) samples for each claimed specimen type and, when determined to be appropriate by FDA, additional characterized clinical samples. The study must be performed on a study population consistent with the intended use population and compare the device performance to results obtained from FDA-accepted comparator methods. Documentation from the clinical studies must include the clinical study protocol (including a predefined statistical analysis plan), study report, testing results, and results of all statistical analyses.
 - iv. A detailed description of the impact of any software, including software applications and hardware-based devices that incorporate software, on the device's functions.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the A device to detect and identify microbial agents in human clinical specimens that cause fever. they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes

and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Bryan Grabias at 240-402-9563.

Sincerely,

Uwe Scherf, M. Sc., Ph. D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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