December 20, 2024

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

Re: K243759
Trade/Device Name: BIOFIRE Blood Culture Identification 2 (BCID2) Panel (RFIT-ASY-0147 (30 pack) RFIT-ASY-0148 (6 pack))
Regulation Number: 21 CFR 866.3365
Regulation Name: Multiplex Nucleic Acid Assay For Identification Of Microorganisms And Resistance Markers From Positive Blood Cultures
Regulatory Class: Class II
Product Code: PEN, PAM, PEO
Dated: December 5, 2024
Received: December 6, 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: 2024.12.20 10:36:58 -05'00'

Bryan Grabias, Ph. D.
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)*
K243759

Device Name
BIOFIRE Blood Culture Identification 2 (BCID2) Panel (RFIT-ASY-0147 (30 pack) RFIT-ASY-0148 (6 pack))

Indications for Use *(Describe)*
The BIOFIRE Blood Culture Identification 2 (BCID2) Panel is a multiplexed nucleic acid test intended for use with BIOFIRE FILMARRAY 2.0 or BIOFIRE FILMARRAY TORCH Systems for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants associated with antimicrobial resistance. The BIOFIRE BCID2 Panel test is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results.
The following organism types and subtypes are identified using the BIOFIRE BCID2 Panel:
Gram Positive Bacteria
Enterococcus faecalis Staphylococcus spp. Streptococcus spp.
Enterococcus faecium Staphylococcus aureus Streptococcus agalactiae (Group B)
Listeria monocytogenes Staphylococcus epidermidis Streptococcus pneumoniae Staphylococcus lugdunensis
Streptococcus pyogenes (Group A)
Gram Negative Bacteria
Acinetobacter calcoaceticus-baumannii complex Enterobacterales
Bacteroides fragilis Enterobacter cloacae complex
Haemophilus influenzae Escherichia coli
Neisseria meningitidis (encapsulated) Klebsiella aerogenes
Pseudomonas aeruginosa Klebsiella oxytoca
Stenotrophomonas maltophilia Klebsiella pneumoniae group
Proteus spp.
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Salmonella spp.
Serratia marcescens
Yeast
Candida albicans Candida krusei Cryptococcus neoformans/gattii
Candida auris Candida parapsilosis
Candida glabrata Candida tropicalis
The BIOFIRE BCID2 Panel contains assays for the detection of genetic determinants associated with resistance to methicillin (mecA/C and mecA/C in conjunction with MREJ), vancomycin (vanA and vanB), ß-lactams including penicillins, cephalosporins, monobactams, and carbapenems (blaCTX-M, blaIMP, blaKPC, blaNDM, blaOXA48-like, blaVIM) to aid in the identification of potentially antimicrobial-resistant organisms in positive blood culture samples. In addition, the panel includes an assay for the detection of the mobilized genetic determinant mcr-1, an emerging marker of public health importance. The antimicrobial resistance gene or marker detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene and marker assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, ß-lactams, and colistin exist.
Antimicrobial Resistance Genes
CTX-M KPC mecA/C NDM vanA/B
IMP mcr-1 mecA/C and MREJ (MRSA) OXA-48-like VIM
The BIOFIRE BCID2 Panel is indicated as an aid in the diagnosis of specific agents of bloodstream infection and results should be used in conjunction with other clinical and laboratory findings. Positive results do not rule out co-infection with organisms not included in the BIOFIRE BCID2 Panel. The BIOFIRE BCID2 Panel is not intended to monitor treatment for bloodstream infection.
Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not detected by the BIOFIRE BCID2 Panel, and for

determination of species detected but not identified within complexes, groups, or genera by the BIOFIRE BCID2 Panel assays.

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® FILMARRAY® BIOFIRE Blood Culture Identification 2 (BCID2) 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 Blood Culture Identification 2 (BCID2) Panel (K193519) with a software update to mitigate a risk of false negative 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:
Karli Plenert, MBA
Telephone: +1 385-414-4985
Email: Karli.Plenert@biomerieux.com

Date Submitted: December 5, 2024

Device Name and Classification:

Trade Name: BIOFIRE® FILMARRAY® Blood Culture Identification 2 (BCID2) Panel

Regulation Number: 21 CFR 866.3365

Classification Name: Multiplex nucleic acid assay for identification of microorganisms and resistance markers from positive blood cultures.

Predicate Devices:

K193519 – BIOFIRE Blood Culture Identification 2 (BCID2) Panel

Background:

In October of 2023, bioMérieux initiated a Field Safety Corrective Action (FDA Recall Event # 93360) due to reports of unexpected/false negative (Not Detected) results for *C. tropicalis* on the BIOFIRE BCID2 Panel when testing Maine Molecular Quality Controls, Inc. (MMQCI) FilmArray BCID2 Control Panel M416, an external control material. In some portion of test runs using the MMQCI material, the *C. tropicalis* synthetic control material is amplified but reported as 'Not Detected' because the melting temperature (Tm) of the amplicon is above the Tm limit assigned to the assay.

Investigation determined two root causes for the intermittent false negative control results: 1) a shift to higher amplicon Tm associated with instrument calibration (FSCA 5788-1) and 2) minor incompatibility between the Tm range assigned to the Ctropicalis assay and the Tm of the amplicon generated by the synthetic control material. Data from the synthetic control material(s) had not been included in the establishment and validation of the assay Tm ranges used for analysis by the pouch module software.

Mitigation of the risk of false negative *C. tropicalis* results from the control material includes correction of instrument calibration and revision of the BCID2 Panel pouch module software to include updates to the Tm range of the Ctropicalis (and other) assays that incorporates the appropriate tolerance to the Tm of synthetic control material sequences.

Summary of Changes

Software Update:

bioMérieux has initiated a software (pouch module) update to adjust the Tm range for a subset of assays following re-analysis to include data generated from synthetic control materials. The revised Tm range(s) mitigate the risk of false negative results associated with amplicon Tm.

Reanalysis of the performance data (clinical and non-clinical/analytical studies) with the modified pouch module software led to a change in sensitivity for *S. epidermidis* from 96.5% [93.0-98.2%] to 96.9% [93.8-98.5%], as documented in the updated BIOFIRE BCID2 instructions for use. Re-analysis did not result in an overall change of the study conclusions or performance claims for the panel.

The pouch module revision also includes the addition of the following note to the results report:

Note: All BIOFIRE BCID2 Panel results are intended to be interpreted in conjunction with Gram stain results. In some cases, the Gram stain result and the BIOFIRE BCID2 Panel result may be discrepant. In these cases, the BIOFIRE BCID2 Panel results should be confirmed, e.g., by culture or other laboratory, epidemiological, or clinical findings. Blood culture media may contain non-viable organisms and/or nucleic acids that may lead to false positive BIOFIRE BCID2 Panel results.

Typically, these false positives present with more than one positive result from the BIOFIRE BCID2 Panel.

Instructions for Use Update:

The instructions for use (IFU) for the BIOFIRE BCID2 Panel has been updated to reflect the very minor adjustment to clinical sensitivity for *S. epidermidis* due to the pouch module update and reanalysis. Additional updates are included for organism descriptions as well as analytical reactivity/specificity tables and descriptions that are driven by post-market monitoring and sequence surveillance programs. Changes include taxonomic updates (new species identification and/or re-classification) as well as adjustments to sequence-based reactivity predictions based on monitoring of available sequence data.

Intended Use:

The BIOFIRE® Blood Culture Identification 2 (BCID2) Panel is a multiplexed nucleic acid test intended for use with BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH Systems for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants associated with antimicrobial resistance. The BIOFIRE BCID2 Panel test is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results. The following organism types and subtypes are identified using the BIOFIRE BCID2 Panel:

Gram Positive Bacteria		
Enterococcus faecalis	*Staphylococcus* spp.	*Streptococcus* spp.
Enterococcus faecium	*Staphylococcus aureus*	*Streptococcus agalactiae* (Group B)
Listeria monocytogenes	*Staphylococcus epidermidis*	*Streptococcus pneumoniae*

	Staphylococcus lugdunensis	*Streptococcus pyogenes* (Group A)
Gram Negative Bacteria		
Acinetobacter calcoaceticus-baumannii complex		*Enterobacterales*
Bacteroides fragilis		*Enterobacter cloacae* complex
Haemophilus influenzae		*Escherichia coli*
Neisseria meningitidis (encapsulated)		*Klebsiella aerogenes*
Pseudomonas aeruginosa		*Klebsiella oxytoca*
Stenotrophomonas maltophilia		*Klebsiella pneumoniae* group
		Proteus spp.
		Salmonella spp.
		Serratia marcescens
Yeast		
Candida albicans	*Candida krusei*	*Cryptococcus neoformans/gattii*
Candida auris	*Candida parapsilosis*	
Candida glabrata	*Candida tropicalis*	

The BIOFIRE BCID2 Panel contains assays for the detection of genetic determinants associated with resistance to methicillin (mecA/C and mecA/C in conjunction with MREJ), vancomycin (vanA and vanB), ß-lactams including penicillins, cephalosporins, monobactams, and carbapenems ($_{bla}$CTX-M, $_{bla}$IMP, $_{bla}$KPC, $_{bla}$NDM, $_{bla}$OXA48-like, $_{bla}$VIM) to aid in the identification of potentially antimicrobial-resistant organisms in positive blood culture samples. In addition, the panel includes an assay for the detection of the mobilized genetic determinant mcr-1, an emerging marker of public health importance. The antimicrobial resistance gene or marker detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene and marker assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, ß-lactams, and colistin exist.

Antimicrobial Resistance Genes				
CTX-M	KPC	*mecA/C*	NDM	*vanA/B*
IMP	*mcr-1*	*mecA/C* and MREJ (MRSA)	OXA-48-like	VIM

The BIOFIRE BCID2 Panel is indicated as an aid in the diagnosis of specific agents of bloodstream infection and results should be used in conjunction with other clinical and laboratory findings. Positive results do not rule out co-infection with organisms not included in the BIOFIRE BCID2 Panel. The BIOFIRE BCID2 Panel is not intended to monitor treatment for bloodstream infection.

Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not detected by the BIOFIRE BCID2 Panel, and for determination of species detected but not identified within complexes, groups, or genera by the BIOFIRE BCID2 Panel assays.

Device Description:

The BIOFIRE Blood Culture Identification 2 (BCID2) Panel is designed to simultaneously identify 43 bacteria and yeast responsible for bloodstream infections, as well as select genetic determinants of antimicrobial resistance (see Table 1), in a timeframe (about an hour) that allows the test results to be used in determining appropriate patient treatment and management. The BIOFIRE BCID2 Panel is performed directly on positive blood culture samples.

The BIOFIRE BCID2 Panel is compatible with BioFire's PCR-based in vitro diagnostic BIOFIRE FILMARRAY 2.0 and FILMARRAY TORCH systems for infectious disease testing. A specific software module (i.e., BIOFIRE BCID2 Panel pouch module) is used to perform BIOFIRE BCID2 Panel testing on these systems.

A test is initiated by loading Hydration Solution into one port of the BIOFIRE pouch and positive blood culture specimen mixed with the provided Sample Buffer into the other port of the BIOFIRE BCID2 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 (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 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 2 outlines the similarities and differences between the modified panels and the predicate panels.

Table 1. Comparison of the BioFire BCID2 Panel and the BioFire BCID2 Panel with Software Update

Element	Predicate: BioFire Blood Culture Identification 2 (BCID2) Panel (K193519)	Current BioFire Blood Culture Identification 2 (BCID2) Panel with software update
Intended Use	The BIOFIRE® Blood Culture Identification 2 (BCID2) Panel is a multiplexed nucleic acid test intended for use with BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® Torch Systems for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants associated with antimicrobial resistance. The BIOFIRE BCID2 Panel test is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results.	Same
Specimen Type	Blood culture samples identified as positive by a continuous monitoring blood culture system.	Same

Element	Predicate: BioFire Blood Culture Identification 2 (BCID2) Panel (K193519)	Current BioFire Blood Culture Identification 2 (BCID2) Panel with software update

Organisms Detected	Gram-positive Bacteria
	• *Enterococcus faecalis*
	• *Enterococcus faecium*
	• *Listeria monocytogenes*
	• *Staphylococcus spp.*
	  • *Staphylococcus aureus*
	  • *Staphylococcus epidermidis*
	  • *Staphylococcus lugdunensis*
	• *Streptococcus spp.*
	  • *Streptococcus agalactiae (Group B)*
	  • *Streptococcus pneumoniae*
	  • *Streptococcus pyogenes (Group A)*
	
	Gram-negative Bacteria
	• *Acinetobacter calcoaceticus-baumannii complex*
	• *Enterobacterales*
	• *Bacteroides fragilis*
	• *Enterobacter cloacae complex*
	• *Haemophilus influenza*
	• *Escherichia coli*
	• *Neisseria meningitidis (encapsulated)*
	• *Klebsiella aerogenes*
	• *Pseudomonas aeruginosa*
	• *Klebsiella oxytoca*
	• *Stenotrophomonas maltophilia*
	• *Klebsiella pneumoniae group*
	• *Proteus spp.*
	• *Salmonella spp.*
	• *Serratia marcescens*
	
	Yeast
	• *Candida albicans*
	• *Candida krusei*
	• *Cryptococcus neoformans/gattii*
	• *Candida auris*
	• *Candida parapsilosis*
	• *Candida glabrata*
	• *Candida tropicalis*
	
	Antimicrobial Resistance Genes
	• *CTX-M*
	• *KPC*
	• *mecA/C*
	• *NDM*
	• *vanA/B*
	• *IMP*
	• *mcr-1*
	• *mecA/C and MREJ (MRSA)*
	• *OXA-48-like*
	• *VIM*
		Same

Analyte	DNA	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 1 hour	Same
Reagent Storage	Room temperature	Same
Sample Preparation Method	Sample Processing is automated in the BIOFIRE System.	Same
Shelf-Life	12 months from Date of Manufacture	Same
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	Same

Element	Predicate: BioFire Blood Culture Identification 2 (BCID2) Panel (K193519)	Current BioFire Blood Culture Identification 2 (BCID2) Panel with software update
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/Low	Same

Conclusion:

The software modification and update to the labeling (instructions for use) do not affect the fundamental scientific technology, overall performance claims, or risk of the BIOFIRE BCID2 Panel. Therefore, the modified BIOFIRE BCID2 Panel performs as well as the predicate device.