



SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K243885

B Applicant

BioFire Diagnostics, LLC

C Proprietary and Established Names

BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PCH	Class II	21 CFR 866.3990 - Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay	MI - Microbiology

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own CLASS II device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
2. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. This minor changes to the software and labeling of the previously cleared BIOFIRE FILMARRAY Gastrointestinal (GI) Panel (K242367) was to mask and then report out only 11 of the 22 targets on the BIOFIRE GI Menu. No** new performance data were reviewed.

3. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.
4. A Design Control Activities Summary which includes:
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.