

**K130914 FILMARRAY BLOOD CULTURE IDENTIFICATION
(BCID) PANEL**Jun 21, 2013
80 days to decisionK130914 · Product code: **PEN** · Microbiology
Source: <https://www.510kdatabase.net/k130914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gram-negative Bacteria And Associated Resistance Markers (PEN)
Date received	Apr 2, 2013
Decision date	Jun 21, 2013
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biofire Diagnostics, Inc.
Location	Salt Lake City, UT, US
Contact	BETH LINGENFELTER
510(k) history	5 submissions · 5 cleared · 2013-2013

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