

K123620 FILMARRAY RESPIRATORY PANEL (RP)Feb 11, 2013
80 days to decisionK123620 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k123620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Nov 23, 2012
Decision date	Feb 11, 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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