

K120413 SIMPLEXA FLU A/B & RSV DIRECT, SIMPLEXA FLU A/B & RSV POSITIVE CONTROL PACKJul 13, 2012
154 days to decisionK120413 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k120413/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Feb 10, 2012
Decision date	Jul 13, 2012
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Focus Diagnostics, Inc.
Location	Cypress, CA, US
Contact	TARA VIVIANI
510(k) history	14 submissions · 13 cleared · 2007-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120413/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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