

**K142365 Simplexa Flu A/B & RSV Direct & Simplexa Flu A/B
RSV Positive Control Pack**Dec 5, 2014
102 days to decisionK142365 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k142365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Aug 25, 2014
Decision date	Dec 5, 2014
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Focus Diagnostics
Location	Cypress, CA, US
Contact	Sharon Young
510(k) history	4 submissions · 3 cleared · 2014-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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