

K152408 Simplexa Flu A/B & RSV Direct and Simplexa Flu A/B & RSV Positive Control Pack

Sep 21, 2015
27 days to decision

K152408 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k152408/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Aug 25, 2015
Decision date	Sep 21, 2015
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k152408/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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