

K102170 SIMPLEXA FLU A/B & RSVNov 24, 2010
114 days to decisionK102170 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k102170/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Aug 2, 2010
Decision date	Nov 24, 2010
Days to decision	114 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

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