

**K201505 Simplexa Flu A/B & RSV Direct Gen II, Simplexa Flu A/B & RSV Positive Control Pack**Aug 22, 2020  
78 days to decisionK201505 · Product code: **OCC** · Microbiology  
Source: <https://www.510kdatabase.net/k201505/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jun 5, 2020
Decision date	Aug 22, 2020
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diasorin Molecular, LLC</b>
Location	Cypress, CA, US
Contact	Sharon Young
510(k) history	13 submissions · 12 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201505/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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