

K252387 Simplexa™ COVID-19/ Flu A/B & RSV Direct (MOL4450)Oct 30, 2025
91 days to decisionK252387 · Product code: **QOF** · Microbiology
Source: <https://www.510kdatabase.net/k252387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF)
Date received	Jul 31, 2025
Decision date	Oct 30, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Simplexa™ COVID-19/ Flu A/B & RSV Positive Control Pack (MOL4460)

APPLICANT

Company	Diasorin Molecular, LLC
Location	Cypress, CA, US
Contact	Michael Treas
510(k) history	13 submissions · 12 cleared · 2018-2025

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