

K220963 Simplexa COVID-19 & Flu A/B DirectMar 17, 2023
350 days to decisionK220963 · Product code: **QOF** · Microbiology
Source: <https://www.510kdatabase.net/k220963/>**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	Apr 1, 2022
Decision date	Mar 17, 2023
Days to decision	350 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220963/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026