

K212147 Simplexa COVID-19 DirectSep 13, 2022
431 days to decisionK212147 · Product code: **QQX** · Microbiology
Source: <https://www.510kdatabase.net/k212147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Specimen Nucleic Acid Sars-cov-2 Test (QQX)
Date received	Jul 9, 2021
Decision date	Sep 13, 2022
Days to decision	431 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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