

K190219 Simplexa VZV Direct, Simplexa VZV Positive Control PackMay 13, 2019
98 days to decisionK190219 · Product code: **PLO** · Microbiology
Source: <https://www.510kdatabase.net/k190219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Meningitis/encephalitis Pathogen Multiplex Nucleic Acid Detection System (PLO)
Date received	Feb 4, 2019
Decision date	May 13, 2019
Days to decision	98 days
Third-party review	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

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