

K192376 Simplexa VZV Swab Direct, Simplexa VZV Positive Control PackNov 26, 2019
88 days to decisionK192376 · Product code: **PGI** · Microbiology
Source: <https://www.510kdatabase.net/k192376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Virus (vzv, Hsv1, Hsv2), Dna Detection Assay For Cutaneous And Mucocutaneous Lesion Samples (PGI)
Date received	Aug 30, 2019
Decision date	Nov 26, 2019
Days to decision	88 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192376/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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