

**K173798 Simplexa HSV 1 & 2 Direct, Simplexa HSV 1 & 2  
Positive Control Pack**Mar 14, 2018  
90 days to decisionK173798 · Product code: **PGI** · Microbiology  
Source: <https://www.510kdatabase.net/k173798/>**SUBMISSION DETAILS**

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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	Dec 14, 2017
Decision date	Mar 14, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173798/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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