

K162451 Solana HSV 1+2/VZV AssayNov 28, 2016
88 days to decisionK162451 · Product code: **PGI** · Microbiology
Source: <https://www.510kdatabase.net/k162451/>**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	Sep 1, 2016
Decision date	Nov 28, 2016
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quidel Corporation
Location	San Diego, CA, US
Contact	Ronald H. Lollar
510(k) history	37 submissions · 35 cleared · 2010-2024

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