

K172509 Sentosa SA201 HSV 1/2 Qualitative PCR TestFeb 1, 2018
164 days to decisionK172509 · Product code: **OQO** · Microbiology
Source: <https://www.510kdatabase.net/k172509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Simplex Virus Nucleic Acid Amplification Assay (OQO)
Date received	Aug 21, 2017
Decision date	Feb 1, 2018
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vela Diagnostics USA, Inc.
Location	Fairfield, NJ, US
Contact	Donald Henton
510(k) history	1 submissions · 1 cleared · 2018-2018

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