

K150962 Simplexa HSV 1 & 2 Direct, Simplexa HSV 1 & 2 Positive Control Pack

Aug 28, 2015
140 days to decision

K150962 · Product code: **OQO** · Microbiology
Source: <https://www.510kdatabase.net/k150962/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Simplex Virus Nucleic Acid Amplification Assay (OQO)
Date received	Apr 10, 2015
Decision date	Aug 28, 2015
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Focus Diagnostics
Location	Cypress, CA, US
Contact	SHARON YOUNG
510(k) history	4 submissions · 3 cleared · 2014-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k150962/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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