

K152353 SeraQuest HSV Type 2 Specific IgGMay 13, 2016
267 days to decisionK152353 · Product code: **MYF** · Microbiology
Source: <https://www.510kdatabase.net/k152353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-2 (MYF)
Date received	Aug 20, 2015
Decision date	May 13, 2016
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quest International, Inc.
Location	Mami, FL, US
Contact	David J Kiefer
510(k) history	3 submissions · 3 cleared · 2016-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152353/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026