

**K111527 MULTICODE-RTX HERPES SIMPLEX VIRUS 1 & 2 KIT**Aug 3, 2011  
63 days to decisionK111527 · Product code: **OQO** · Microbiology  
Source: <https://www.510kdatabase.net/k111527/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Simplex Virus Nucleic Acid Amplification Assay (OQO)
Date received	Jun 1, 2011
Decision date	Aug 3, 2011
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Eragen Biosciences, Inc.</b>
Location	Madison, WI, US
Contact	DAVID LIM
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111527/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 18, 2026