

**K100336 MULTICODE - RTX HERPES SIMPLEX VIRUS 1 AND 2
KIT, MODEL 3711**

May 12, 2010
96 days to decision

K100336 · Product code: **OQO** · Microbiology
Source: <https://www.510kdatabase.net/k100336/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Simplex Virus Nucleic Acid Amplification Assay (OQO)
Date received	Feb 5, 2010
Decision date	May 12, 2010
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eragen Biosciences
Location	Madison, WI, US
Contact	RANDAL VADER
510(k) history	1 submissions · 1 cleared · 2010-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k100336/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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