

**K120986 STRATIFY JCV DXSELECT**Aug 16, 2012  
136 days to decisionK120986 · Product code: **OYP** · Microbiology  
Source: <https://www.510kdatabase.net/k120986/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-jcv Antibody Detection Assay (OYP)
Date received	Apr 2, 2012
Decision date	Aug 16, 2012
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Focus Diagnostics, Inc.</b>
Location	Cypress, CA, US
Contact	TARA VIVIANI
510(k) history	14 submissions · 13 cleared · 2007-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120986/> 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 May 14, 2026