

**K103112 AFFYMETRIX GENE PROFILING REAGENTS**May 4, 2011  
195 days to decisionK103112 · Product code: **OVA** · Immunology  
Source: <https://www.510kdatabase.net/k103112/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complete Gene Expression Profiling Accessory Reagents (OVA)
Date received	Oct 21, 2010
Decision date	May 4, 2011
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Affymetrix, Inc.</b>
Location	Santa Clara, CA, US
Contact	MAUREEN MENDE
Website	<a href="http://www.affymetrix.com/">http://www.affymetrix.com/</a>
510(k) history	4 submissions · 2 cleared · 2004-2014

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103112/> 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