

**K110616 THERMO SCIENTIFIC MAS OMNI-IMMUNE, MAS OMNI  
IMMUNE PRO**Jun 29, 2011  
118 days to decisionK110616 · Product code: JJY · Chemistry  
Source: <https://www.510kdatabase.net/k110616/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Mar 3, 2011
Decision date	Jun 29, 2011
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Microgenics Corp.</b>
Location	Concord, CA, US
Contact	LISA CHARTER
510(k) history	107 submissions · 106 cleared · 1985-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110616/> 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