

**K123343 THERMO SCIENTIFIC QMS TACROLIMUS ASSAY AND CALIBRATORS**Jul 11, 2013  
253 days to decisionK123343 · Product code: **MLM** · Toxicology  
Source: <https://www.510kdatabase.net/k123343/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Tacrolimus (MLM)
Date received	Oct 31, 2012
Decision date	Jul 11, 2013
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Microgenics Corp.</b>
Location	Concord, CA, US
Contact	KAREN LEE
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/k123343/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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