

K050206 CEDIA TACROLIMUS ASSAYMar 15, 2005
46 days to decisionK050206 · Product code: **MLM** · Toxicology
Source: <https://www.510kdatabase.net/k050206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Tacrolimus (MLM)
Date received	Jan 28, 2005
Decision date	Mar 15, 2005
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050206/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026