

**K994029 MDI SM TEST**Jan 11, 2000  
46 days to decisionK994029 · Product code: **LLL** · Immunology  
Source: <https://www.510kdatabase.net/k994029/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Nov 26, 1999
Decision date	Jan 11, 2000
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Micro Detect, Inc.</b>
Location	Tustin, CA, US
Contact	MEHDI ALEM
510(k) history	11 submissions · 11 cleared · 1998-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k994029/> 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 June 29, 2026