

**K920385 ANTI-ENA ANTIBODY TEST (SM)**Mar 30, 1992  
60 days to decisionK920385 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k920385/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jan 30, 1992
Decision date	Mar 30, 1992
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Immco Diagnostics, Inc.</b>
Location	Buffalo, NY, US
Contact	SUSAN DRASNY
510(k) history	55 submissions · 55 cleared · 1988-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k920385/> 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 30, 2026