

**K970220 IS-ANTI-SM TEST SYSTEM**Apr 8, 1997  
77 days to decisionK970220 · Product code: **LLL** · Immunology  
Source: <https://www.510kdatabase.net/k970220/>**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 21, 1997
Decision date	Apr 8, 1997
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diamedix Corp.</b>
Location	Miami, FL, US
Contact	LYNNE STIRLING, PH.D.
510(k) history	68 submissions · 68 cleared · 1986-2011

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