

**K980759 DIAMEDIX IS-ENA-6 SCREEN TEST SYSTEM**Apr 23, 1998  
55 days to decisionK980759 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k980759/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Feb 27, 1998
Decision date	Apr 23, 1998
Days to decision	55 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
510(k) history	68 submissions · 68 cleared · 1986-2011

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