

K994424 DIAMEDIX IS-ANTI-DSDNA TEST SYSTEM

Feb 18, 2000
50 days to decision

K994424 · Product code: **LRM** · Immunology
Source: <https://www.510kdatabase.net/k994424/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Dec 30, 1999
Decision date	Feb 18, 2000
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k994424/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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