

**K943291 ANTI DS-DNA**Dec 2, 1994  
147 days to decisionK943291 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k943291/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jul 8, 1994
Decision date	Dec 2, 1994
Days to decision	147 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	TIMOTHY J PERKO
510(k) history	164 submissions · 164 cleared · 1984-2002

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