

K921658 ANTI-DSDNA ANTIBODY TESTMar 22, 1993
349 days to decisionK921658 · Product code: **LSW** · Immunology
Source: <https://www.510kdatabase.net/k921658/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody, Antigen And Control (LSW)
Date received	Apr 7, 1992
Decision date	Mar 22, 1993
Days to decision	349 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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