

K920384 ANIT-ENA ANTIBODY TEST [SS-B (LA)]Mar 30, 1992
60 days to decisionK920384 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k920384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jan 30, 1992
Decision date	Mar 30, 1992
Days to decision	60 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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