

K895339 ANTI-SS-A (RO) AND ANTI-SS-B (LA) ANTIBODY TESTOct 4, 1989
34 days to decisionK895339 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k895339/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Aug 31, 1989
Decision date	Oct 4, 1989
Days to decision	34 days
Third-party review	No

APPLICANT

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

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