

K943585 ANTI-HISTONE ANIBODY TESTJan 20, 1995
182 days to decisionK943585 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k943585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Jul 22, 1994
Decision date	Jan 20, 1995
Days to decision	182 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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