

K030929 ANA DETECTMay 2, 2003
39 days to decisionK030929 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k030929/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Mar 24, 2003
Decision date	May 2, 2003
Days to decision	39 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Orgentec Diagnostika GmbH
Location	Minneapolis, MN, US
Contact	MICHAEL H FOLEY
510(k) history	3 submissions · 3 cleared · 2003-2010

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