

K833148 ENZYME ANA TEST SYSTEMNov 21, 1983
67 days to decisionK833148 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k833148/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Sep 15, 1983
Decision date	Nov 21, 1983
Days to decision	67 days
Third-party review	No

APPLICANT

Company	Immuno Concepts, Inc.
Location	Mchenry, IL, US
510(k) history	36 submissions · 36 cleared · 1981-2001

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Device record: <https://www.510kdatabase.net/k833148/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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