

K822346 HISTIMUNE ENZYME-ANA TESTOct 8, 1982
63 days to decisionK822346 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k822346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Aug 6, 1982
Decision date	Oct 8, 1982
Days to decision	63 days
Third-party review	No

APPLICANT

Company	Icl Scientific
Location	Mchenry, IL, US
510(k) history	48 submissions · 48 cleared · 1976-1988

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Device record: <https://www.510kdatabase.net/k822346/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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