

K842533 AMIZYME-ANDNA TEST KITSep 20, 1984
84 days to decisionK842533 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k842533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Jun 28, 1984
Decision date	Sep 20, 1984
Days to decision	84 days
Third-party review	No

APPLICANT

Company	Amico Lab, Inc.
Location	Mchenry, IL, US
510(k) history	32 submissions · 32 cleared · 1982-1985

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