

K842532 AMIZYME-ANA TEST KIT

Sep 20, 1984
84 days to decision

K842532 · Product code: LJM · Immunology
Source: <https://www.510kdatabase.net/k842532/>

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

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k842532/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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