

**K862969 ANA-ENZYME IMMUNOASSAY (ANA-EIA)
DIAGNOSTIC KIT**Oct 24, 1986
79 days to decisionK862969 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k862969/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Aug 6, 1986
Decision date	Oct 24, 1986
Days to decision	79 days
Third-party review	No

APPLICANT

Company	Biohytech International, Inc.
Location	Chicago, IL, US
Contact	HIRSCH, PHD
510(k) history	7 submissions · 7 cleared · 1986-1987

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