

K870456 DNP EIA DIAGNOSTIC KITMar 17, 1987
55 days to decisionK870456 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k870456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Jan 21, 1987
Decision date	Mar 17, 1987
Days to decision	55 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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