

K870455 SM EIA DIAGNOSTIC KITMar 17, 1987
55 days to decisionK870455 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k870455/>**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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k870455/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026