

**K870457 RNP EIA DIAGNOSTIC KIT**Mar 17, 1987  
55 days to decisionK870457 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k870457/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k870457/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026