FDA 510(k) Premarket Notification

K870457 RNP EIA DIAGNOSTIC KIT

CLEARED

Mar 17, 1987
55 days to decision

K870457 · Product code: **LJM** · Immunology
Source: https://www.510kdatabase.net/k870457/

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