

K902915 ANTI-SCI-70 MICROASSAYSep 6, 1990
65 days to decisionK902915 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k902915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Jul 3, 1990
Decision date	Sep 6, 1990
Days to decision	65 days
Third-party review	No

APPLICANT

Company	Diamedix Corp.
Location	Miami, FL, US
Contact	KIEFER, PHD
510(k) history	68 submissions · 68 cleared · 1986-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k902915/>; 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 20, 2026