

K970239 IS-ANTI-SCL-70 TEST SYSTEM (720-280)Apr 8, 1997
77 days to decisionK970239 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k970239/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jan 21, 1997
Decision date	Apr 8, 1997
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diamedix Corp.
Location	Miami, FL, US
Contact	LYNNE STIRLING, PH.D.
510(k) history	68 submissions · 68 cleared · 1986-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970239/> 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