

K001875 DIAMEDIX IS-RUBELLA IGM CAPTURE TEST SYSTEMAug 21, 2000
62 days to decisionK001875 · Product code: **LFX** · Microbiology
Source: <https://www.510kdatabase.net/k001875/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jun 20, 2000
Decision date	Aug 21, 2000
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001875/> 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