

K934550 IMMUNOCARD MYCOPLASMASep 20, 1994
363 days to decisionK934550 · Product code: **LJZ** · Microbiology
Source: <https://www.510kdatabase.net/k934550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Mycoplasma Spp. (LJZ)
Date received	Sep 22, 1993
Decision date	Sep 20, 1994
Days to decision	363 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Meridian Diagnostics, Inc.
Location	Walker, MI, US
Contact	ALLEN D NICKOL
510(k) history	92 submissions · 92 cleared · 1980-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934550/> 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 May 14, 2026