

K961508 IMMUNOCARD H. PYLORIJan 21, 1997
277 days to decisionK961508 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k961508/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Apr 19, 1996
Decision date	Jan 21, 1997
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961508/> 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