

K945558 PREMIER(TM) H. PYLORYMar 3, 1995
109 days to decisionK945558 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k945558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Nov 14, 1994
Decision date	Mar 3, 1995
Days to decision	109 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

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