

K990462 IS H. PYLORI IGG ELISA TEST SYSTEMSep 3, 1999
203 days to decisionK990462 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k990462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Feb 12, 1999
Decision date	Sep 3, 1999
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Columbia Bioscience, Inc.
Location	Frederick, MD, US
Contact	NORMAN JENKINS
510(k) history	13 submissions · 13 cleared · 1996-1999

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