

K001460 VIDAS H. PYLORI IGG (HPY) ASSAY, MODEL 30 192Oct 4, 2000
147 days to decisionK001460 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k001460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	May 10, 2000
Decision date	Oct 4, 2000
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	JANET CONNOLLY
510(k) history	251 submissions · 250 cleared · 1983-2026

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