

K012411 HP-ONESep 25, 2001
57 days to decisionK012411 · Product code: **LYR** · Microbiology
Source: <https://www.510kdatabase.net/k012411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Jul 30, 2001
Decision date	Sep 25, 2001
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gi Supply
Location	Camp Hill, PA, US
Contact	FRANK CARTER
510(k) history	8 submissions · 8 cleared · 1992-2020

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