

K934863 FLEXSURE HPMay 18, 1994
218 days to decisionK934863 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k934863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Oct 12, 1993
Decision date	May 18, 1994
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smithkline Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	MICHAEL A DANIEL
510(k) history	42 submissions · 42 cleared · 1976-1996

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