

K942974 PYLORISSET DRYApr 5, 1995
289 days to decisionK942974 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k942974/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Jun 20, 1994
Decision date	Apr 5, 1995
Days to decision	289 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Orion Diagnostica, Div. Orion Corp.
Location	02101 Espoo, FI
Contact	TIMO RAINES
510(k) history	4 submissions · 4 cleared · 1995-2003

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