

K971537 PYLORISSET EIA-G (68926)Jun 27, 1997
60 days to decisionK971537 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k971537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Apr 28, 1997
Decision date	Jun 27, 1997
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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