

K972981 SHIELD HELICO-G2 ELISA KITMar 17, 1998
218 days to decisionK972981 · Product code: **LYR** · Microbiology
Source: <https://www.510kdatabase.net/k972981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Aug 11, 1997
Decision date	Mar 17, 1998
Days to decision	218 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shield Diagnostics, Ltd.
Location	Scotland, KN
Contact	EILEEN MCCAFFERTY
510(k) history	27 submissions · 27 cleared · 1990-2000

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