

K041238 HELICOBACTER PYLORI IGG ELISADec 13, 2004
216 days to decisionK041238 · Product code: **LYR** · Microbiology
Source: <https://www.510kdatabase.net/k041238/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	May 11, 2004
Decision date	Dec 13, 2004
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biohit Plc
Location	Neptune, NJ, US
Contact	ROBERT P GEARTY
510(k) history	1 submissions · 1 cleared · 2004-2004

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