

K110745 HELICOBACTER PYLORI ELISA IGG TEST KITMar 2, 2012
351 days to decisionK110745 · Product code: LZR · Microbiology
Source: <https://www.510kdatabase.net/k110745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Mar 17, 2011
Decision date	Mar 2, 2012
Days to decision	351 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gold Standard Diagnostics
Location	Davis, CA, US
Contact	NAPOLEON MONCE
510(k) history	14 submissions · 14 cleared · 2012-2021

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