

**K110899 GOLD STANDARD DIAGNOSTICS H. PYLORI ELISA
IGA TEST KIT**Feb 1, 2012
308 days to decisionK110899 · Product code: LZR · Microbiology
Source: <https://www.510kdatabase.net/k110899/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Mar 30, 2011
Decision date	Feb 1, 2012
Days to decision	308 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110899/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026