

**K161139 LIAISON H. pylori IgG, LIAISON H. pylori IgG Control Set**Jul 22, 2016  
91 days to decisionK161139 · Product code: LYR · Microbiology  
Source: <https://www.510kdatabase.net/k161139/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Apr 22, 2016
Decision date	Jul 22, 2016
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DiaSorin, Inc.</b>
Location	Ellicott City, MD, US
Contact	JOHN WALTER
510(k) history	70 submissions · 69 cleared · 1998-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161139/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 2, 2026