

**K153661 ImmunoCard STAT! HpSA**Mar 14, 2016  
84 days to decisionK153661 · Product code: LYR · Microbiology  
Source: <https://www.510kdatabase.net/k153661/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Dec 21, 2015
Decision date	Mar 14, 2016
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Meridian Bioscience, Inc.</b>
Location	Cincinnati, OH, US
Contact	Susan Rolih
Website	<a href="https://www.meridianbioscience.com">https://www.meridianbioscience.com</a>
510(k) history	38 submissions · 37 cleared · 2003-2025

Meridian Bioscience, Inc. is a diagnostic and life science solutions company with a manufacturing facility in Cincinnati, US. The company develops integrated diagnostic products and molecular reagents for clinical and research applications. Meridian has received FDA 510(k) clearances from total submissions since 2003. The company specializes exclusively in Microbiology devices, including molecular detection assays, pathogen identification systems, and diagnostic analyzers. The latest clearance in 2025 reflects continued regulatory activity and product innovation. Recent c...

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