

**K905049 QUIDEL HELICOBACTER PYLORI POSTIVE/NEGATIVE  
CONTR**May 7, 1991  
180 days to decisionK905049 · Product code: LYR · Microbiology  
Source: <https://www.510kdatabase.net/k905049/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Nov 8, 1990
Decision date	May 7, 1991
Days to decision	180 days
Third-party review	No

**APPLICANT**

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Company	<b>Quidel Corp.</b>
Location	Washington, DC, US
Contact	CRAIG E WATSON
510(k) history	93 submissions · 93 cleared · 1983-2013

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905049/>; 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 8, 2026