

**K952517 QUICKVUE ONE-STEP HELICOBACTOR PYLORI TEST**Feb 6, 1996  
251 days to decisionK952517 · Product code: LZR · Microbiology  
Source: <https://www.510kdatabase.net/k952517/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	May 31, 1995
Decision date	Feb 6, 1996
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k952517/> 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