

**K881595 QUIDEL PREGNANCY TEST**May 27, 1988  
45 days to decisionK881595 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k881595/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 12, 1988
Decision date	May 27, 1988
Days to decision	45 days
Third-party review	No

**APPLICANT**

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Company	<b>Quidel Corp.</b>
Location	Washington, DC, US
Contact	Robin Weiner
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/k881595/>; 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