

**K883316 QUIDEL PREGNANCY TEST CONTROL**Sep 22, 1988  
48 days to decisionK883316 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k883316/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Aug 5, 1988
Decision date	Sep 22, 1988
Days to decision	48 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/k883316/>; 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