

**K973858 CARDS Q.S. HCG SERUM/URINE**Nov 26, 1997  
48 days to decisionK973858 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k973858/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 9, 1997
Decision date	Nov 26, 1997
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary
Other names	CONCISE PERFORMANCE PLUS HCG-COMBO

**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/k973858/> 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