

K890615 DIRECTIGEN1-2-3 BHCG PREGNANCY TESTApr 18, 1989
70 days to decisionK890615 · Product code: **JHI** · ChemistrySource: <https://www.510kdatabase.net/k890615/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received | Feb 7, 1989 |
| Decision date | Apr 18, 1989 |
| Days to decision | 70 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k890615/>; Data sourced from FDA 510(k) public records (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. - Generated June 8, 2026