

K020801 QUICKVUE ONE-STEP HCG-COMBOMay 17, 2002
66 days to decisionK020801 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k020801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Mar 12, 2002
Decision date	May 17, 2002
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quidel Corp.
Location	Washington, DC, US
Contact	JENNIFER S HANKARD
510(k) history	93 submissions · 93 cleared · 1983-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k020801/> 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