FDA 510(k) Premarket Notification

K020801 QUICKVUE ONE-STEP HCG-COMBO

CLEARED

May 17, 2002
66 days to decision

K020801 · 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