FDA 510(k) Premarket Notification

K973841 QUICKVUE ONE-STEP HCG-COMBO

CLEARED

Dec 1, 1997
54 days to decision

K973841 · Product code: **JHI** · Chemistry
Source: https://www.510kdatabase.net/k973841/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 8, 1997
Decision date	Dec 1, 1997
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Quidel Corp.**
Location	Washington, DC, US
Contact	ROBING WEINER
510(k) history	93 submissions · 93 cleared · 1983-2013