K974821 BLUETEST(R) PREGNANCY TEST, RAPIDVUE(R) PREGNANCY TEST

CLEARED

Jan 26, 1998
34 days to decision

K974821 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k974821/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Dec 23, 1997
Decision date	Jan 26, 1998
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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