FDA 510(k) Premarket Notification

K981722 QUIDEL HOME PREGNANCY TEST

CLEARED

Jun 3, 1998
19 days to decision

K981722 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k981722/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	May 15, 1998
Decision date	Jun 3, 1998
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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