FDA 510(k) Premarket Notification

K831051 HOME PREGNANCY TEST KIT HPK #1

CLEARED

May 18, 1983
47 days to decision

K831051 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k831051/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Apr 1, 1983
Decision date	May 18, 1983
Days to decision	47 days
Third-party review	No

APPLICANT

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