FDA 510(k) Premarket Notification

K833466 EARLY PREGNANCY DETECTION TEST KIT

CLEARED

Nov 25, 1983
50 days to decision

K833466 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k833466/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Oct 6, 1983
Decision date	Nov 25, 1983
Days to decision	50 days
Third-party review	No

APPLICANT

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