

K831108 HOME PREGNANCY TEST KITMay 18, 1983
43 days to decisionK831108 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k831108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Apr 5, 1983
Decision date	May 18, 1983
Days to decision	43 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k831108/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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