

K981892 QUICK & SURE ONESTEP HOME PREGNANCY TESTAug 18, 1998
81 days to decisionK981892 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k981892/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	May 29, 1998
Decision date	Aug 18, 1998
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Abacus Diagnostics
Location	West Hills, CA, US
Contact	PAMELA BAGARIA
510(k) history	1 submissions · 1 cleared · 1998-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981892/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026