

K925189 PREGNAGEN 1-STEP PREGNANCY TESTJan 6, 1993
85 days to decisionK925189 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k925189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Oct 13, 1992
Decision date	Jan 6, 1993
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biogenex Laboratories
Location	Mchenry, IL, US
Contact	SHUNG-HO CHANG
510(k) history	12 submissions · 12 cleared · 1981-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k925189/> 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 May 14, 2026