

K973208 FIRST SIGNOct 20, 1997
54 days to decisionK973208 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k973208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Aug 27, 1997
Decision date	Oct 20, 1997
Days to decision	54 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Texas Immunology, Inc.
Location	Mchenry, IL, US
Contact	CHARLES W GILL
510(k) history	27 submissions · 27 cleared · 1982-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973208/> 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 28, 2026