

K962521 FACTPLUS ONE STEP PREGNANCY TESTJul 29, 1996
40 days to decisionK962521 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k962521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jun 19, 1996
Decision date	Jul 29, 1996
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Direct Access Diagnostics
Location	Bridgewater, NJ, US
Contact	MARYLOU PANICO
510(k) history	2 submissions · 2 cleared · 1996-1996

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