

K964108 FACT PLUS PREGNANCY TESTNov 18, 1996
34 days to decisionK964108 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k964108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Oct 15, 1996
Decision date	Nov 18, 1996
Days to decision	34 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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