

K954178 OSOM PREGNANCY TESTOct 23, 1995
48 days to decisionK954178 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k954178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Sep 5, 1995
Decision date	Oct 23, 1995
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wyntek Diagnostics, Inc.
Location	San Diego, CA, US
Contact	SHU-CHING CHENG
510(k) history	12 submissions · 12 cleared · 1995-2000

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