FDA 510(k) Premarket Notification

K023037 MID STREAM PREGNANCY TEST

CLEARED

Apr 9, 2003
209 days to decision

K023037 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k023037/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Sep 12, 2002
Decision date	Apr 9, 2003
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Advanced Diagnostics, Inc.**
Location	Richland, WA, US
Contact	D.M. CHOUHAN
510(k) history	4 submissions · 4 cleared · 2000-2003

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k023037/ 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 19, 2026