FDA 510(k) Premarket Notification

K062703 ONE STEP HCG PREGNANCY TEST

CLEARED

Jul 23, 2007
315 days to decision

K062703 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k062703/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Sep 11, 2006
Decision date	Jul 23, 2007
Days to decision	315 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ai DE Diagnostic Co., Ltd.**
Location	Iowa City, IA, US
Contact	LIN WANG
510(k) history	1 submissions · 1 cleared · 2007-2007