FDA 510(k) Premarket Notification

K023638 CASSETTE/URINE HCG

CLEARED

Jan 3, 2003
65 days to decision

K023638 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k023638/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Oct 30, 2002
Decision date	Jan 3, 2003
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ind Diagnostic, Inc.**
Location	Delta, B.C., CA
Contact	DAVID LEE
510(k) history	8 submissions · 8 cleared · 2003-2012