

**K052694 ONE STEP HCG PREGNANCY TEST - 2000 MIU/ML,
MODEL 100 SERIES.**Dec 16, 2005
79 days to decisionK052694 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k052694/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Sep 28, 2005
Decision date	Dec 16, 2005
Days to decision	79 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052694/> 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 June 15, 2026