

**K050741 IND ONE STEP HCG PREGNANCY TEST - CASSETTE
FORMAT**May 16, 2005
56 days to decisionK050741 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k050741/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received | Mar 21, 2005 |
| Decision date | May 16, 2005 |
| Days to decision | 56 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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