

K832557 FERTITELL DIRECT PREGNANCY TEST #1100Sep 12, 1983
42 days to decisionK832557 · Product code: **JHJ** · Chemistry
Source: <https://www.510kdatabase.net/k832557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agglutination Method, Human Chorionic Gonadotropin (JHJ)
Date received	Aug 1, 1983
Decision date	Sep 12, 1983
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Stanbio Laboratory
Location	Mchenry, IL, US
510(k) history	47 submissions · 47 cleared · 1977-2009

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Device record: <https://www.510kdatabase.net/k832557/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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