

K842544 STANBIO QUICK-TELL MONOCLONAL INDIRECTSep 21, 1984
81 days to decisionK842544 · Product code: **JHJ** · Chemistry
Source: <https://www.510kdatabase.net/k842544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agglutination Method, Human Chorionic Gonadotropin (JHJ)
Date received	Jul 2, 1984
Decision date	Sep 21, 1984
Days to decision	81 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k842544/>; 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 23, 2026