

K853258 BETA-HCG MICROTITER PREGNANCY TESTOct 1, 1985
60 days to decisionK853258 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k853258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 2, 1985
Decision date	Oct 1, 1985
Days to decision	60 days
Third-party review	No

APPLICANT

Company	Modern Diagnostics, Inc.
Location	Sacramento, CA, US
Contact	ROBERT L BUCK
510(k) history	5 submissions · 5 cleared · 1985-1985

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853258/>; 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 30, 2026