

K850531 LEECO CONCEP-7-BHCG EIAApr 2, 1985
50 days to decisionK850531 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k850531/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Feb 11, 1985
Decision date	Apr 2, 1985
Days to decision	50 days
Third-party review	No

APPLICANT

Company	Leeco Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	JAMES P LEE
510(k) history	49 submissions · 49 cleared · 1979-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k850531/>, 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