

K926342 VISTA(R) HUMAN CHORIONIC GONADOTROPIN (HCG) ASSAY

Feb 17, 1993
62 days to decision

K926342 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k926342/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Dec 17, 1992
Decision date	Feb 17, 1993
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	PAUL L ROGERS
510(k) history	448 submissions · 447 cleared · 1976-2001

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k926342/> 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 28, 2026