

K970396 HUMAN CHORIONIC GONADOTROPIN CALIBRATORFeb 20, 1997
17 days to decisionK970396 · Product code: **JIW** · Chemistry
Source: <https://www.510kdatabase.net/k970396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Surrogate (JIW)
Date received	Feb 3, 1997
Decision date	Feb 20, 1997
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dade Chemistry Systems, Inc.
Location	Newark, DE, US
Contact	REBECCA S AYASH
510(k) history	13 submissions · 13 cleared · 1996-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970396/> 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