

K970387 HUMAN CHORIONIC GONADOTROPIN METHODMar 10, 1997
35 days to decisionK970387 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k970387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Feb 3, 1997
Decision date	Mar 10, 1997
Days to decision	35 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/k970387/> 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