

K946224 CERTAIN(R) ELITE LEVEL 1, 2 AND 3Jan 30, 1995
77 days to decisionK946224 · Product code: **JJS** · Chemistry
Source: <https://www.510kdatabase.net/k946224/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controls For Blood-gases, (assayed And Unassayed) (JJS)
Date received	Nov 14, 1994
Decision date	Jan 30, 1995
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ciba Corning Diagnostics Corp.
Location	East Walpole, MA, US
Contact	STEVEN R RAKITIN
510(k) history	125 submissions · 125 cleared · 1986-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k946224/> 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 May 26, 2026