

K896236 COBAS READY BUN REAGENTFeb 27, 1990
120 days to decisionK896236 · Product code: **JGZ** · Chemistry
Source: <https://www.510kdatabase.net/k896236/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	O-phthalaldehyde, Urea Nitrogen (JGZ)
Date received	Oct 30, 1989
Decision date	Feb 27, 1990
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	ALEX WESOLOWSKI
510(k) history	296 submissions · 296 cleared · 1983-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k896236/> 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 23, 2026