

K895526 COBAS READY GLUCOSE REAGENTOct 16, 1989
34 days to decisionK895526 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k895526/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Sep 12, 1989
Decision date	Oct 16, 1989
Days to decision	34 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

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