

K863223 DIMENSION-WBGMar 10, 1987
201 days to decisionK863223 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k863223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Aug 21, 1986
Decision date	Mar 10, 1987
Days to decision	201 days
Third-party review	No

APPLICANT

Company	Dimension Diagnostics
Location	St. Charles, MO, US
Contact	CLYDE E HAM
510(k) history	8 submissions · 8 cleared · 1985-1987

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k863223/>; 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