

K982303 PRECISION PCX POINT OF CARE MANAGEMENT SYSTEM , QC MANAGER DATA MANAGER SYSTEM, PRECISION G PLUS BLOOD GLUCOSE TEST STDec 8, 1998
160 days to decisionK982303 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k982303/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Jul 1, 1998
Decision date	Dec 8, 1998
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medisense, Inc.
Location	Cambridge, MA, US
Contact	MICHAEL HALPIN
510(k) history	15 submissions · 15 cleared · 1990-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982303/> 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 28, 2026