

K843003 GLUCOSE AUTO& STAT GA-1120Sep 28, 1984
60 days to decisionK843003 · Product code: **CGA** · Toxicology
Source: <https://www.510kdatabase.net/k843003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Jul 30, 1984
Decision date	Sep 28, 1984
Days to decision	60 days
Third-party review	No

APPLICANT

Company	Kyoto Diagnostics, Inc.
Location	Walker, MI, US
510(k) history	11 submissions · 11 cleared · 1984-1986

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k843003/> 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 29, 2026