

K073416 ARKRAY GLUCOCARD 01 BLOOD MONITORING SYSTEMJun 13, 2008
193 days to decisionK073416 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k073416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 3, 2007
Decision date	Jun 13, 2008
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arkray Factory USA, Inc.
Location	Edina, MN, US
Contact	TOM SPEIKERS
510(k) history	9 submissions · 9 cleared · 2007-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k073416/> 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 19, 2026