

**K091102 ASSURE PLATINUM AND GLUCOCARD VITAL BLOOD
GLUCOSE MONITORING SYSTEMS**Oct 23, 2009
190 days to decisionK091102 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k091102/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Apr 16, 2009
Decision date	Oct 23, 2009
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091102/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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