

K142336 GLUCOCARD 01 Blood Glucose Monitoring System/ReliOn Confirm Blood Glucose Monitoring SystemSep 17, 2014
27 days to decisionK142336 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k142336/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Aug 21, 2014
Decision date	Sep 17, 2014
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arkray Factory, Inc.
Location	Edina, MN, US
Contact	Kazuya Yorimitsu
510(k) history	6 submissions · 6 cleared · 2014-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142336/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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