

**K124021 ARKRAY GLUCOCARD 01 BLOOD GLUCOSE MONITORING SYSTEM AND RELION CONFIRM BLOOD GLUCOSE MONITORING SYSTEM**Jun 30, 2014  
550 days to decisionK124021 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k124021/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 27, 2012
Decision date	Jun 30, 2014
Days to decision	550 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arkray Factory, Inc.</b>
Location	Edina, MN, US
Contact	LONNA M DENDOOVEN
510(k) history	6 submissions · 6 cleared · 2014-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k124021/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026