

**K063771 GLUCOCARD X-METER BLOOD GLUCOSE MONITORING SYSTEM**Aug 9, 2007  
231 days to decisionK063771 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k063771/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Dec 21, 2006
Decision date	Aug 9, 2007
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063771/>. 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 19, 2026