

**K170064 GLUCOCARD W Blood Glucose Monitoring System**

Aug 16, 2017  
219 days to decision

K170064 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k170064/>

**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	Jan 9, 2017
Decision date	Aug 16, 2017
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arkray Factory, Inc.</b>
Location	Edina, MN, US
Contact	KAZUYA YORIMITSU
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/k170064/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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