

**K183306 GLUCOCARD® W onyx Blood Glucose Monitoring System**Apr 10, 2019  
133 days to decisionK183306 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k183306/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Nov 28, 2018
Decision date	Apr 10, 2019
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Arkra Y America, Inc.</b>
Contact	Dhwani Thakkar

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183306/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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