

**K160944 ACCU-CHEK Guide Blood Glucose Monitoring System**Aug 31, 2016  
148 days to decisionK160944 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k160944/>**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	Apr 5, 2016
Decision date	Aug 31, 2016
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diabetes Care, Inc.</b>
Location	Indianapolis,, IN, US
Contact	Khone Saysana
510(k) history	9 submissions · 9 cleared · 2015-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160944/> 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 May 26, 2026