

**K181131 Accu-Chek Guide Me Blood Glucose Monitoring System**Dec 13, 2018  
227 days to decisionK181131 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k181131/>**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	Apr 30, 2018
Decision date	Dec 13, 2018
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diabetes Care</b>
Location	Indianapolis, IN, US
Contact	Ginger Emrich
510(k) history	1 submissions · 1 cleared · 2018-2018

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181131/>. 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