

**K161299 BGM014 Blood Glucose Monitoring System, BGM014 Pro Blood Glucose Monitoring System**Dec 23, 2016  
228 days to decisionK161299 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k161299/>**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	May 9, 2016
Decision date	Dec 23, 2016
Days to decision	228 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Apex BioTechnology Corp.</b>
Location	Plymouth, MN, US
Contact	Hsue-mei Lee
510(k) history	35 submissions · 35 cleared · 2001-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161299/> 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 14, 2026