

**K151658 Gmate Origin Blood Glucose Monitoring System**Dec 1, 2015  
165 days to decisionK151658 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k151658/>**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	Jun 19, 2015
Decision date	Dec 1, 2015
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philosys, Inc.</b>
Location	New York, NY, US
Contact	LINDA CHAN
510(k) history	4 submissions · 4 cleared · 2014-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151658/> 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 3, 2026