

**K043543 BLOOD GLUCOSE MONITORING SYSTEM**Apr 8, 2005  
109 days to decisionK043543 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k043543/>**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	Dec 20, 2004
Decision date	Apr 8, 2005
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Healthcare, Inc.</b>
Location	New York, NY, US
Contact	EDWARD LETKO
510(k) history	3 submissions · 3 cleared · 2003-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043543/> 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 29, 2026