

**K081703 MYGLUCOHEALTH GLUCOSE MONITORING SYSTEMS**Jan 8, 2009  
205 days to decisionK081703 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k081703/>**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 17, 2008
Decision date	Jan 8, 2009
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Entra Health Systems, Ltd.</b>
Location	Pleasanton, CA, US
Contact	CARLOS GONZALEZ
510(k) history	1 submissions · 1 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081703/> 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 23, 2026