

**K133790 IHEALTH ALIGN MINI GLUCO-MONITORING SYSTEM**May 22, 2014  
164 days to decisionK133790 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k133790/>**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	Dec 9, 2013
Decision date	May 22, 2014
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Andon Health Co, Ltd.</b>
Location	Tiajin, CN
Contact	YI LIU
510(k) history	92 submissions · 92 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133790/> 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 6, 2026