

**K150833 iHealth Align Gluco-Monitoring System, iHealth BG5
wireless Smart Gluco-Monitoring System, iHealth BG5L
wireless Smart Gluco-Monitoring System**Dec 4, 2015
249 days to decisionK150833 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k150833/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 30, 2015
Decision date	Dec 4, 2015
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Andon Health Co, Ltd.
Location	Tiajin, CN
Contact	Yi Liu
510(k) history	92 submissions · 92 cleared · 2008-2025

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