

K170231 iHealth Align Gluco-Monitoring System (BG1)Sep 15, 2017
233 days to decisionK170231 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k170231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Jan 25, 2017
Decision date	Sep 15, 2017
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary
Other names	iHealth Wireless Smart Gluco-Monitoring System (BG5)

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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