

K153286 iHealth Align Gluco-Monitoring systemAug 19, 2016
281 days to decisionK153286 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k153286/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Nov 12, 2015
Decision date	Aug 19, 2016
Days to decision	281 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153286/> Data sourced from FDA 510(k) public records (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. - Generated June 2, 2026