

**K181070 iHealth Wireless Smart Gluco-Monitoring System
(iHealth Gluco+)**Feb 1, 2019
284 days to decisionK181070 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k181070/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Apr 23, 2018
Decision date	Feb 1, 2019
Days to decision	284 days
Third-party review	No
Combination product	No
PCCP authorized	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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