

K100937 PC CARE BLOOD GLUCOSE DATA MANAGEMENT SOFTWAREDec 21, 2010
260 days to decisionK100937 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k100937/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Apr 5, 2010
Decision date	Dec 21, 2010
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	I-Sens, Inc.
Location	Seoul, KR
Contact	HYUN OH
510(k) history	27 submissions · 27 cleared · 2008-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100937/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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