

K121133 CARESENS N VOICE BLOOD GLUCOSE MONITORING SYSTEMJul 10, 2012
88 days to decisionK121133 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k121133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Apr 13, 2012
Decision date	Jul 10, 2012
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121133/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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