

**K120351 CARESENS N POP BLOOD GLUCOSE MONITORING
SYSTEM CARESENS N POP BLOOD GLUCOSE METER
CARESENS N BLOOD GLUCOSE TEST STRIP CA**

May 3, 2012
87 days to decision

K120351 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k120351/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Feb 6, 2012
Decision date	May 3, 2012
Days to decision	87 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.net

Device record: <https://www.510kdatabase.net/k120351/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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