

K120759 CARESENS N MINI BLOOD GLUCOSE MONITORING SYSTEM, MINI BLOOD GLUCOSE METER, BLOOD GLUCOSE TEST STRIP, CONTROL SOLUTION

Jun 5, 2012
84 days to decision

K120759 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k120759/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Mar 13, 2012
Decision date	Jun 5, 2012
Days to decision	84 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/k120759/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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