

K121654 AUTO-CHEK BLOOD GLUCOSE MONITORING SYSTEM, METER, TEST STRIP. AUTO-CHECK CONTROL SOLUTIONSep 5, 2012
92 days to decisionK121654 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k121654/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Jun 5, 2012
Decision date	Sep 5, 2012
Days to decision	92 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

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