

**K083468 CARESENS N BLOOD GLUCOSE MONITORING SYSTEM, CARESENS N METER, MODEL GM5051A OR GM5051B OR GM5051C (COLOR)**Feb 10, 2009  
78 days to decisionK083468 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k083468/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Nov 24, 2008
Decision date	Feb 10, 2009
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083468/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026