

K080923 CARESENS BLOOD GLUCOSE MONITORING SYSTEMOct 17, 2008
198 days to decisionK080923 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k080923/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Apr 2, 2008
Decision date	Oct 17, 2008
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary
Other names	CARESENS II METER, MODEL GM505C; CARESENS POP METER, MODEL GM505EA OR GM505EB

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/k080923/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026