

**K103396 COOL BLOOD GLUCOSE MONITORING SYSTEM,
BLOOD GLUCOSE METER, COOL CONTROL SOLUTION**Sep 27, 2011
312 days to decisionK103396 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k103396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Nov 19, 2010
Decision date	Sep 27, 2011
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	I-Sens, Inc.
Location	Seoul, KR
Contact	STANLEY R GOODMAN
510(k) history	27 submissions · 27 cleared · 2008-2023

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