

**K151164 Assure Prism multi Blood Glucose Monitoring System**Aug 7, 2015  
98 days to decisionK151164 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k151164/>**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	May 1, 2015
Decision date	Aug 7, 2015
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>I-Sens, Inc.</b>
Location	Seoul, KR
Contact	JOON HO JUNG
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/k151164/> 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 June 4, 2026