

**K180866 CareSens S Fit Blood Glucose Monitoring System**Aug 31, 2018  
151 days to decisionK180866 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k180866/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Apr 2, 2018
Decision date	Aug 31, 2018
Days to decision	151 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/k180866/> 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