

# K192859 CareSens S Clear BT Blood Glucose Monitoring System

Jan 24, 2020  
112 days to decisionK192859 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k192859/>**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	Oct 4, 2019
Decision date	Jan 24, 2020
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

**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/k192859/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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