

K193590 CareSens S Fit BT Blood Glucose Monitoring SystemJan 17, 2020
25 days to decisionK193590 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k193590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Dec 23, 2019
Decision date	Jan 17, 2020
Days to decision	25 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	I-Sens, Inc.
Location	Seoul, KR
Contact	Joon Ho Jung
510(k) history	27 submissions · 27 cleared · 2008-2023

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