

**K201394 CareSens N Feliz Blood Glucose Monitoring System,
CareSens N Feliz BT Blood Glucose Monitoring System**Oct 5, 2021
496 days to decisionK201394 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k201394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	May 27, 2020
Decision date	Oct 5, 2021
Days to decision	496 days
Third-party review	No
Combination product	No
PCCP authorized	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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