

K170614 CareSens N Premier Blood Glucose Monitoring System, CareSens N Premier BT Blood Glucose Monitoring System

Oct 19, 2017
232 days to decision

K170614 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k170614/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 1, 2017
Decision date	Oct 19, 2017
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k170614/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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