

K130696 CARESENS N LINK BLOOD GLUCOSE MONITORING SYSTEM

Aug 21, 2013
160 days to decision

K130696 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k130696/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 14, 2013
Decision date	Aug 21, 2013
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary
Other names	CARESENS N LINK MULTI BLOOD BLUCOSE MONITORING SYSTEM

APPLICANT

Company	I-Sens, Inc.
Location	Seoul, KR
Contact	CHAE YUN LIM
510(k) history	27 submissions · 27 cleared · 2008-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k130696/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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