

K230625 ReliOn Premier BLU Blood Glucose Monitoring SystemAug 10, 2023
157 days to decisionK230625 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k230625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 6, 2023
Decision date	Aug 10, 2023
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	I-Sens, Inc.
Location	Seoul, KR
Contact	H.S. Yoo
510(k) history	27 submissions · 27 cleared · 2008-2023

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