

K192220 ReliOn Premier Classic Blood Glucose Monitoring System

Dec 13, 2019
120 days to decisionK192220 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k192220/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Aug 15, 2019
Decision date	Dec 13, 2019
Days to decision	120 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192220/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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