

K181273 GLUCOCARD Shine Connex Blood Glucose Monitoring System, GLUCOCARD Shine Express Blood Glucose Monitoring System

Nov 1, 2018
171 days to decision

K181273 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k181273/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	May 14, 2018
Decision date	Nov 1, 2018
Days to decision	171 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/k181273/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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