

K203711 IWL2020 Blood Glucose Monitoring SystemMay 6, 2022
501 days to decisionK203711 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k203711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Dec 21, 2020
Decision date	May 6, 2022
Days to decision	501 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diabetes Care, Inc.
Location	Indianapolis,, IN, US
Contact	Kelly Brennan
510(k) history	9 submissions · 9 cleared · 2015-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203711/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026