

K213131 Accu-Chek Guide Solo diabetes manager blood glucose monitoring systemAug 10, 2023
682 days to decisionK213131 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k213131/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Sep 27, 2021
Decision date	Aug 10, 2023
Days to decision	682 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diabetes Care GmbH
Location	Mannheim, DE
Contact	Wolfgang Handel
510(k) history	2 submissions · 2 cleared · 2023-2023

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