

K081389 ACCU-CHEK COMPACT PLUS BLOOD GLUCOSE MONITORING SYSTEMJul 15, 2008
57 days to decisionK081389 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k081389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	May 19, 2008
Decision date	Jul 15, 2008
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	Scott Thiel
Website	https://diagnostics.roche.com
510(k) history	182 submissions · 180 cleared · 2005-2026

Roche Diagnostics is a Swiss multinational healthcare company specializing in diagnostic devices and solutions. The company operates its U.S. diagnostics division from Indianapolis. Roche Diagnostics maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 2005. The company's portfolio spans chemistry devices, immunology assays, microbiology testing, and hematology systems. The latest clearance in 2026 reflects continued innovation and regulatory engagement. Recent cleared devices include glucose monitoring systems, elec...

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Device record: <https://www.510kdatabase.net/k081389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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