FDA 510(k) Premarket Notification

CLEARED

K121679 ACCU-CHEK INFORM II BLOOD GLUCOSE MONITORING SYSTEM

Oct 11, 2012
126 days to decision

K121679 · Product code: **NBW** · Chemistry
Source: https://www.510kdatabase.net/k121679/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Jun 7, 2012
Decision date	Oct 11, 2012
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics**
Location	Indianapolos, IN, US
Contact	MIKE FLIS
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k121679/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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