FDA 510(k) Premarket Notification

# K101299 ACCU-CHEK AVIVA PLUS BLOOD GLUCOSE MONITORING SYSTEM

**CLEARED**

Sep 21, 2011
499 days to decision

K101299 · Product code: **LFR** · Chemistry
Source: https://www.510kdatabase.net/k101299/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Glucose Dehydrogenase, Glucose (LFR) |
| Date received | May 10, 2010 |
| Decision date | Sep 21, 2011 |
| Days to decision | 499 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Roche Diagnostics** |
| Location | Indianapolos, IN, US |
| Contact | ANDRENE HERON |
| 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...