

K252323 cobas pulse blood glucose monitoring systemJun 12, 2026
322 days to decisionK252323 · Product code: **PZI** · Chemistry
Source: <https://www.510kdatabase.net/k252323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Prescription Use Blood Glucose Meter For Near-patient Testing (PZI)
Date received	Jul 25, 2025
Decision date	Jun 12, 2026
Days to decision	322 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	Teresa Carrow
Website	https://diagnostics.roche.com
510(k) history	183 submissions · 181 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...