FDA 510(k) Premarket Notification

CLEARED

K220272 cobas pulse blood glucose monitoring system

Apr 26, 2024
816 days to decision

K220272 · Product code: **PZI** · Chemistry
Source: https://www.510kdatabase.net/k220272/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Prescription Use Blood Glucose Meter For Near-patient Testing (PZI)
Date received	Jan 31, 2022
Decision date	Apr 26, 2024
Days to decision	816 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	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...