FDA 510(k) Premarket Notification

CLEARED

K052101 C.F.A.S. (CALIBRATOR FOR AUTOMATED SYSTEMS) HBA1C

Aug 26, 2005
23 days to decision

K052101 · Product code: **KRZ** · Chemistry
Source: https://www.510kdatabase.net/k052101/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator For Hemoglobin And Hematocrit Measurement (KRZ)
Date received	Aug 3, 2005
Decision date	Aug 26, 2005
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics**
Location	Indianapolos, IN, US
Contact	THERESA M AMBROSE
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...