

**K101456 ROCHE DIAGNOSTICS CALIBRATOR FOR  
AUTOMATED SYSTEMS, ROCHE DIAGNOSTICS CALIBRATOR  
CALIBRATOR FOR AUTOMATED SYSTEM**Sep 8, 2010  
105 days to decisionK101456 · Product code: **JIX** · Chemistry  
Source: <https://www.510kdatabase.net/k101456/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	May 26, 2010
Decision date	Sep 8, 2010
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics</b>
Location	Indianapolis, IN, US
Contact	Susan Hollandbeck
Website	<a href="https://diagnostics.roche.com">https://diagnostics.roche.com</a>
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...