

**K090939 ROCHE C.F.A.S. DAT QUALITATIVE PLUS CLINICAL
CALBRATOR AND CONTROL SET DAT CLINICAL, MODELS
04590856 190, 04500873 190**Jun 18, 2009
76 days to decisionK090939 · Product code: **DKB** · Chemistry
Source: <https://www.510kdatabase.net/k090939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Apr 3, 2009
Decision date	Jun 18, 2009
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	MICHELLE L NEFF
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...