

**K093867 ROCHE ORAL FLUID OPIATES, DAT QUAL CAL A,
DAT CONTROL SET A AND DAT SQ CAL A**Feb 11, 2011
402 days to decisionK093867 · Product code: **DJG** · Chemistry
Source: <https://www.510kdatabase.net/k093867/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jan 5, 2010
Decision date	Feb 11, 2011
Days to decision	402 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	MICHELLE LEE 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k093867/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026