

K110446 ROCHE ORAL FLUID AMPHETAMINE, ROCHE ORAL FLUID DAT QUAL CAL B, ROCHE ORAL FLUID DAT CONTROL SET B, AND ROCHE ORAL FLUIDMay 3, 2011
76 days to decisionK110446 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k110446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Feb 16, 2011
Decision date	May 3, 2011
Days to decision	76 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...