

K112528 ELECSYS T4 CALCHECK 5Oct 18, 2011
48 days to decisionK112528 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k112528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Aug 31, 2011
Decision date	Oct 18, 2011
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corporation
Location	Indianapolis, IN, US
Contact	Michael Leather
510(k) history	6 submissions · 6 cleared · 2007-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112528/> 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 5, 2026