

K132828 ELECSYS CALCITONINDec 4, 2013
86 days to decisionK132828 · Product code: **JKR** · Chemistry
Source: <https://www.510kdatabase.net/k132828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Calcitonin (JKR)
Date received	Sep 9, 2013
Decision date	Dec 4, 2013
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary
Other names	IMMUNOASSAY, CALSET, CALCHECK 5; ELECSYS PRECICONTROL VARIA 3

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	KELLI TURNER
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...