FDA 510(k) Premarket Notification

CLEARED

K141143 COBAS C TINA-QUANT CYSTATIN C GEN.2 ASSAY, C.F.A.S. CYSTATIN C CALIBRATOR, CYSTATIN C GEN.2 CONTROL SET

Jul 17, 2014
76 days to decision

K141143 · Product code: **NDY** · Chemistry
Source: https://www.510kdatabase.net/k141143/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	May 2, 2014
Decision date	Jul 17, 2014
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics**
Location	Indianapolos, IN, US
Contact	KHOA TRAN
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...