

**K072437 ELECSYS PROBPN II, PRECICONTROL CARDIAC II,
PROBPN II CALSET**Feb 5, 2008
166 days to decisionK072437 · Product code: **NBC** · Chemistry
Source: <https://www.510kdatabase.net/k072437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Natriuretic Peptide (NBC)
Date received	Aug 23, 2007
Decision date	Feb 5, 2008
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	KAY TAYLOR
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/k072437/>. 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 25, 2026