

**K223637 Elecsys proBNP II, Elecsys proBNP II STAT**Jul 21, 2023  
228 days to decisionK223637 · Product code: **NBC** · Chemistry  
Source: <https://www.510kdatabase.net/k223637/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Natriuretic Peptide (NBC)
Date received	Dec 5, 2022
Decision date	Jul 21, 2023
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics</b>
Location	Indianapolis, IN, US
Contact	Jane Phillips
Website	<a href="https://diagnostics.roche.com">https://diagnostics.roche.com</a>
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k223637/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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