

**K092649 ELECSYS PROBNP II STAT IMMUNOASSAY AND  
ELECSYS PROBNP II CALSET, MODELS 05390109-160,  
04842472-190**

Feb 4, 2010  
160 days to decision

K092649 · Product code: **NBC** · Chemistry  
Source: <https://www.510kdatabase.net/k092649/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Natriuretic Peptide (NBC)
Date received	Aug 28, 2009
Decision date	Feb 4, 2010
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	JANE E PHILLIPS
510(k) history	264 submissions · 263 cleared · 1999-2013

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

Device record: <https://www.510kdatabase.net/k092649/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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