

**K022516 ELECSYS PROBNP IMMUNOASSAY**Nov 19, 2002  
112 days to decisionK022516 · Product code: **NBC** · Chemistry  
Source: <https://www.510kdatabase.net/k022516/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Test, Natriuretic Peptide (NBC)    |
| Date received         | Jul 30, 2002                       |
| Decision date         | Nov 19, 2002                       |
| Days to decision      | 112 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Roche Diagnostics Corp.</b>            |
| Location       | Indianapolis, IN, US                      |
| Contact        | ROBERT A GREGG                            |
| 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/k022516/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026