

**K111905 INTELLIVUE GUARDIAN SOFTWARE MODEL 866009,  
INTELLIVUE CL SP02 POD MODEL 865215, INTELLIVUE CL  
NBP POD MODEL 865216**Oct 4, 2011  
91 days to decisionK111905 · Product code: **DXJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k111905/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Abbreviated                              |
| Device classification | Display, Cathode-ray Tube, Medical (DXJ) |
| Date received         | Jul 5, 2011                              |
| Decision date         | Oct 4, 2011                              |
| Days to decision      | 91 days                                  |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Philips Medizinsysteme Boeblingen GmbH, Cardiac AN</b> |
| Location       | Boeblingen, Baden-Wuerttemberg, DE                        |
| Contact        | MARKUS STACHA   |
| 510(k) history | 25 submissions · 25 cleared · 2007-2014                   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111905/> 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 May 24, 2026