

**K162148 Allura Xper R9**Nov 23, 2016  
114 days to decisionK162148 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k162148/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Abbreviated                                    |
| Device classification | Interventional Fluoroscopic X-ray System (OWB) |
| Date received         | Aug 1, 2016                                    |
| Decision date         | Nov 23, 2016                                   |
| Days to decision      | 114 days                                       |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Philips Medical Systems Netherlands BV</b> |
| Location       | Best Noord-Brabant, NL                        |
| Contact        | Jeanette Becker                               |
| 510(k) history | 5 submissions · 5 cleared · 2014-2016         |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162148/> 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 16, 2026