

**K150306 D2RS\_AT Digital Dynamic Remote System**Oct 10, 2015  
243 days to decisionK150306 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k150306/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | System, X-ray, Fluoroscopic, Image-intensified (JAA) |
| Date received         | Feb 9, 2015  |
| Decision date         | Oct 10, 2015   |
| Days to decision      | 243 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Stephanix Radiological Solutions</b> |
| Location       | La Ricamarie, FR                        |
| Contact        | SANDIE PERRET                           |
| 510(k) history | 1 submissions · 1 cleared · 2015-2015   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150306/> 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