

**K142100 AIXPLORER**Nov 20, 2014  
111 days to decisionK142100 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k142100/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received         | Aug 1, 2014                                       |
| Decision date         | Nov 20, 2014                                      |
| Days to decision      | 111 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Supersonic Imagine</b>               |
| Location       | Aix-En-Provence Cedex, FR               |
| Contact        | AURELIE GRUENER                         |
| 510(k) history | 16 submissions · 16 cleared · 2009-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142100/> 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 26, 2026