

**K161066 SpotLight CT**Aug 10, 2016  
117 days to decisionK161066 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k161066/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received         | Apr 15, 2016                              |
| Decision date         | Aug 10, 2016                              |
| Days to decision      | 117 days                                  |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Arineta , Ltd.</b>                 |
| Location       | Caesarea, IL                          |
| Contact        | Ehud Dafni                            |
| 510(k) history | 5 submissions · 5 cleared · 2016-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161066/> 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