

**K180125 PowerLook Density Assessment Software**Apr 5, 2018  
79 days to decisionK180125 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k180125/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Jan 16, 2018                                 |
| Decision date         | Apr 5, 2018                                  |
| Days to decision      | 79 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Icad, Inc.</b>                       |
| Location       | Beavercreek, OH, US                     |
| Contact        | John DeLucia                            |
| 510(k) history | 14 submissions · 14 cleared · 2004-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180125/> 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