

K211506 PowerLook Density Assessment V4.0Jul 12, 2021
59 days to decisionK211506 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k211506/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received | May 14, 2021 |
| Decision date | Jul 12, 2021 |
| Days to decision | 59 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Icad, Inc. |
| Location | Beavercreek, OH, US |
| Contact | Heather Reed |
| 510(k) history | 14 submissions · 14 cleared · 2004-2024 |

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