

**K121293 CS-SERIES-FP WITH 3030+OPTION**Jul 26, 2012  
87 days to decisionK121293 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k121293/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | System, X-ray, Fluoroscopic, Image-intensified (JAA) |
| Date received         | Apr 30, 2012   |
| Decision date         | Jul 26, 2012   |
| Days to decision      | 87 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Omega Medical Imaging, LLC</b>     |
| Location       | Sanford, FL, US                       |
| Contact        | BRIAN J FLEMING                       |
| 510(k) history | 7 submissions · 7 cleared · 2012-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121293/> 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