

**K173076 CURA 16**Oct 4, 2018  
370 days to decisionK173076 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k173076/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received         | Sep 29, 2017                              |
| Decision date         | Oct 4, 2018                               |
| Days to decision      | 370 days                                  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary                                   |
| Other names           | ScintCare CT16                            |

**APPLICANT**

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Fmi Medical Systems, Inc.</b>      |
| Location       | Solon, OH, US                         |
| Contact        | Scott LeMaster                        |
| 510(k) history | 2 submissions · 2 cleared · 2018-2020 |

**REGULATORY CONSULTANT**

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|-----------------|----------------------------------|
| Consulting firm | <b>FDA 510k Consultants, LLC</b> |
| Contact         | Paul McFeely                     |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173076/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026