

**K252526 Rapid DeltaFuse**Aug 26, 2025  
15 days to decisionK252526 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k252526/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Aug 11, 2025                                 |
| Decision date         | Aug 26, 2025                                 |
| Days to decision      | 15 days                                      |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ischemaview, Inc.</b>                |
| Location       | Irvine, CA, US                          |
| Contact        | James Rosa                              |
| 510(k) history | 21 submissions · 21 cleared · 2013-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252526/> 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 13, 2026