

**K911339 SHIMADZU X-RAY HIGH-VOLTAGE GENERATOR  
XUD150K**Apr 16, 1991  
21 days to decisionK911339 · Product code: **IZO** · Radiology  
Source: <https://www.510kdatabase.net/k911339/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | Generator, High-voltage, X-ray, Diagnostic (IZO) |
| Date received         | Mar 26, 1991                                     |
| Decision date         | Apr 16, 1991                                     |
| Days to decision      | 21 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shimadzu Medical Systems</b>         |
| Location       | Gardena, CA, US                         |
| Contact        | DE MINT                                 |
| 510(k) history | 90 submissions · 90 cleared · 1989-2008 |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911339/> 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 18, 2026