

**K981055 XKNIFE-4**Sep 29, 1998  
190 days to decisionK981055 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k981055/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Accelerator, Linear, Medical (IYE) |
| Date received         | Mar 23, 1998                       |
| Decision date         | Sep 29, 1998                       |
| Days to decision      | 190 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Radionics, Inc.</b>                  |
| Location       | Walker, MI, US                          |
| Contact        | LISA MISTERKA BENATI                    |
| 510(k) history | 56 submissions · 56 cleared · 1982-2003 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981055/> 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 19, 2026