

**K000057 RADIONICS LUMBOPERITONEAL SHUNT**Mar 20, 2000  
70 days to decisionK000057 · Product code: **JXG** · Neurology  
Source: <https://www.510kdatabase.net/k000057/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional  |
| Device classification | Shunt, Central Nervous System And Components (JXG) |
| Date received         | Jan 10, 2000                                       |
| Decision date         | Mar 20, 2000                                       |
| Days to decision      | 70 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Radionics, Inc.</b>                  |
| Location       | Walker, MI, US                          |
| Contact        | KEVIN K O'CONNELL                       |
| 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/k000057/> 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