

**K180945 LUTRONIC GENIUS Radiofrequency System**Dec 10, 2018  
243 days to decisionK180945 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180945/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received         | Apr 11, 2018   |
| Decision date         | Dec 10, 2018   |
| Days to decision      | 243 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Lutronic Corporation</b>             |
| Location       | North Reading, MA, US                   |
| Contact        | Jhung Won Vojir                         |
| 510(k) history | 29 submissions · 29 cleared · 2007-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180945/> 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 14, 2026