

**K251243 OneRF Trigeminal Nerve Radiofrequency Probes**Aug 15, 2025  
115 days to decisionK251243 · Product code: **GXI** · Neurology  
Source: <https://www.510kdatabase.net/k251243/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Probe, Radiofrequency Lesion (GXI) |
| Date received         | Apr 22, 2025                       |
| Decision date         | Aug 15, 2025                       |
| Days to decision      | 115 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Neuroone Medical Technologies Corp.</b> |
| Location       | Eden Prairie, MN, US                       |
| Contact        | Debra Kridner                              |
| 510(k) history | 4 submissions · 4 cleared · 2021-2025      |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251243/> 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