

**K053214 THERAKNIT GARMENT ELECTRODE**Dec 20, 2005  
33 days to decisionK053214 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k053214/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Electrode, Cutaneous (GXY)         |
| Date received         | Nov 17, 2005                       |
| Decision date         | Dec 20, 2005                       |
| Days to decision      | 33 days                            |
| Third-party review    | Yes                                |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Neurotron Medical</b>              |
| Location       | Ewing, NJ, US                         |
| Contact        | JACK GULDALIAN                        |
| 510(k) history | 2 submissions · 2 cleared · 1997-2005 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053214/> 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 June 29, 2026