

**K243678 TalisMann Neuromodulation System**Jul 3, 2025  
218 days to decisionK243678 · Product code: **GZF** · Neurology  
Source: <https://www.510kdatabase.net/k243678/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                          |
| Submission type       | Traditional   |
| Device classification | Stimulator, Peripheral Nerve, Implanted (pain Relief) (GZF) |
| Date received         | Nov 27, 2024  |
| Decision date         | Jul 3, 2025   |
| Days to decision      | 218 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Bioventus, LLC</b>                 |
| Location       | Durham, NC, US                        |
| Contact        | Sageev George                         |
| 510(k) history | 5 submissions · 5 cleared · 2017-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243678/> 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