

**K243613 Patch-TEA (Model TRI-21)**Apr 9, 2025  
138 days to decisionK243613 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k243613/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                        |
| Submission type       | Traditional   |
| Device classification | Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH) |
| Date received         | Nov 22, 2024  |
| Decision date         | Apr 9, 2025   |
| Days to decision      | 138 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Transtimulation Research, Inc.</b> |
| Location       | Oklahoma City, OK, US                 |
| Contact        | Victor Pikov                          |
| 510(k) history | 2 submissions · 2 cleared · 2023-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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