

K243982 Nicolet EDXJan 22, 2025
30 days to decisionK243982 · Product code: **GWF** · Neurology
Source: <https://www.510kdatabase.net/k243982/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Stimulator, Electrical, Evoked Response (GWF) |
| Date received | Dec 23, 2024 |
| Decision date | Jan 22, 2025 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Natus Neurology Incorporated |
| Location | Middleton, WI, US |
| Contact | Judy Samson |
| 510(k) history | 5 submissions · 5 cleared · 2013-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243982/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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