

K172919 EV-804 OTC Pain Relief TENSApr 19, 2018
206 days to decisionK172919 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k172919/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH) |
| Date received | Sep 25, 2017 |
| Decision date | Apr 19, 2018 |
| Days to decision | 206 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Everyway Medical Instruments Co.,Ltd |
| Location | Taipei Hsien,, TW |
| Contact | Paul Hung |
| 510(k) history | 29 submissions · 29 cleared · 2001-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172919/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026