

K151034 PainKARENov 21, 2015
218 days to decisionK151034 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k151034/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH) |
| Date received | Apr 17, 2015 |
| Decision date | Nov 21, 2015 |
| Days to decision | 218 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Triowave Technologies |
| Location | Fremont, CA, US |
| Contact | Huiyou Zhu |
| 510(k) history | 1 submissions · 1 cleared · 2015-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151034/> 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 June 3, 2026