

K213835 TENS & EMS DeviceMar 3, 2022
84 days to decisionK213835 · Product code: **NUH** · Physical MedicineSource: <https://www.510kdatabase.net/k213835/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH) |
| Date received | Dec 9, 2021 |
| Decision date | Mar 3, 2022 |
| Days to decision | 84 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shenzhen Jian Feng Electronic Technology Co., Ltd. |
| Location | Baoan District, Shenzhen City, CN |
| Contact | Feng Wen |
| 510(k) history | 4 submissions · 4 cleared · 2021-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213835/> 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 27, 2026