

K150386 Tyece OTC TENS DeviceNov 5, 2015
260 days to decisionK150386 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k150386/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH) |
| Date received | Feb 18, 2015 |
| Decision date | Nov 5, 2015 |
| Days to decision | 260 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Tyece , Ltd. |
| Location | Kowloon, HK |
| Contact | Parshid Falahati |
| 510(k) history | 3 submissions · 3 cleared · 2015-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150386/> 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 28, 2026