

K253896 TENS/EMS device (GUSE01)Mar 4, 2026
89 days to decisionK253896 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k253896/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH) |
| Date received | Dec 5, 2025 |
| Decision date | Mar 4, 2026 |
| Days to decision | 89 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Globalcare Medical Technology Co., Ltd. |
| Location | Zhongshan City, CN |
| Contact | Valentina Sassi |
| 510(k) history | 5 submissions · 5 cleared · 2020-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253896/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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