

**K250053 TENS AND EMS (TENS and Muscle Stimulator)
(JT8012, JT8012B)**May 9, 2025
119 days to decisionK250053 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k250053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jan 10, 2025
Decision date	May 9, 2025
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shenzhen Jiantuo Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Jinliang Zou
510(k) history	3 submissions · 3 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai CV Technology Co., Ltd.
Contact	Doris Dong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250053/> 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 13, 2026