FDA 510(k) Premarket Notification

CLEARED

K250360 TENS AND EMS (TENS and Muscle Stimulator) (JT8012C,JT8016,JT9020E,JT9026)

May 11, 2025
90 days to decision

K250360 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k250360/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Feb 10, 2025
Decision date	May 11, 2025
Days to decision	90 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	Jin Liang 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