

K251187 3 in 1 TENS UNIT (TC1241, TC2241, TS1241)Jul 28, 2025
102 days to decisionK251187 · Product code: **NUH** · Physical Medicine
Source: <https://www.510kdatabase.net/k251187/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Apr 17, 2025
Decision date	Jul 28, 2025
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Changsha Anxiang Medical Technology Co., Ltd.
Location	Changsha, CN
Contact	William Fu
510(k) history	8 submissions · 8 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Manton Business and Technology Services
Contact	Melody Huang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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