

K250759 3 in 1 TENS UNITJun 13, 2025
92 days to decisionK250759 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k250759/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Mar 13, 2025
Decision date	Jun 13, 2025
Days to decision	92 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250759/> 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