

**K242787 Tens & Ems Device (TU1080)**Dec 18, 2024  
93 days to decisionK242787 · Product code: **NGX** · Physical Medicine  
Source: <https://www.510kdatabase.net/k242787/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Stimulator, Muscle, Powered, For Muscle Conditioning (NGX) |
| Date received         | Sep 16, 2024   |
| Decision date         | Dec 18, 2024   |
| Days to decision      | 93 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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

**REGULATORY CONSULTANT**

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|-----------------|--|
| Consulting firm | <b>Manton Business and Technology Services</b> |
| Contact         | Huang Melody                                   |

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242787/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026