

**K212184 TENS and EMS Stimulation (OTC)**Apr 1, 2022  
262 days to decisionK212184 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k212184/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jul 13, 2021
Decision date	Apr 1, 2022
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Changsha Yuwen Medical Equipment Co., Ltd.</b>
Location	Changsha, CN
Contact	Dahui Chen
510(k) history	4 submissions · 4 cleared · 2022-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Microkn Business Consulting (Shanghai) Co., Ltd.</b>
Contact	Eva Li

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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212184/> 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 27, 2026