

**K222867 AD-2126 Transcutaneous Electrical Nerve Stimulators  
(TENS)**Dec 21, 2022  
90 days to decisionK222867 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k222867/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 22, 2022
Decision date	Dec 21, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Andon Health Co, Ltd.</b>
Location	Tiajin, CN
Contact	Liu Yi
510(k) history	92 submissions · 92 cleared · 2008-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222867/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026