

**K242815 POCKET TENS (EP-300)**Dec 17, 2024  
90 days to decisionK242815 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k242815/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 18, 2024
Decision date	Dec 17, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hivox Biotek, Inc.</b>
Location	Taipei, TW
Contact	Leslie Peng
510(k) history	17 submissions · 17 cleared · 2002-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242815/> 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