

**K222870 Transcutaneous Electrical Nerve Stimulator, Model:  
KTR-4031, KTR-4032, KTR-4012, KTR-4015, KTR-4029,  
KTR-4027, KTR-4026, KTR-4021, KTR-4034, KTR-4036,  
KTR-4037, KTR-4039**May 10, 2023  
230 days to decisionK222870 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k222870/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 22, 2022
Decision date	May 10, 2023
Days to decision	230 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shenzhen Kentro Medical Electronics Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Zewu Zhang
510(k) history	10 submissions · 10 cleared · 2017-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222870/> 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 25, 2026