

**K220997 Wireless TENS/EMS, Bruno, Aela**Sep 1, 2022  
150 days to decisionK220997 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k220997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Apr 4, 2022
Decision date	Sep 1, 2022
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zmi Electronics , Ltd.</b>
Location	Kaohsiung, TW
Contact	Lawerence Liu
510(k) history	1 submissions · 1 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220997/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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