

**K172809 OTC Combo TENS/EMS System**Oct 18, 2017  
30 days to decisionK172809 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k172809/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 18, 2017
Decision date	Oct 18, 2017
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Well-Life Healthcare Limited</b>
Location	Kowloon, HK
Contact	Chin-Chih Hsieh
510(k) history	22 submissions · 22 cleared · 2006-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172809/> 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 14, 2026