

**K181849 iStim S2 OTC Pain Relief TENS**Aug 10, 2018  
30 days to decisionK181849 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k181849/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jul 11, 2018
Decision date	Aug 10, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Everyway Medical Instruments Co., Ltd.</b>
Location	New Taipei City, TW
Contact	Paul Hung
510(k) history	2 submissions · 2 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181849/> 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 30, 2026