

**K190347 HIVOX OTC Electrical Stimulator**Mar 15, 2019  
29 days to decisionK190347 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k190347/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Feb 14, 2019
Decision date	Mar 15, 2019
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190347/> 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 26, 2026