

**K190988 GIM-STIM OTC TENS/EMS System**Aug 16, 2019  
123 days to decisionK190988 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k190988/>**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 15, 2019
Decision date	Aug 16, 2019
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Gemore Technology Co, Ltd.</b>
Location	Tan Shui, Taipei Hsien, TW
Contact	Boden S.P. Lai
510(k) history	14 submissions · 14 cleared · 2003-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190988/> 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 June 18, 2026