

**K220152 TENS & PMS (Model:SM9089, SM9587, SM9592, SM9555)**Apr 19, 2022  
90 days to decisionK220152 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k220152/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jan 19, 2022
Decision date	Apr 19, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hong Qiangxing (Shenzhen) Electronics Limited</b>
Location	Shanghai, CN
Contact	Xu jianhua
510(k) history	9 submissions · 9 cleared · 2013-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai CV Technology Co., Ltd.</b>
Contact	Doris Dong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220152/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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