

K233067 Wireless TENS & EMS (Model SM9110,SM9113,SM9116)Jul 19, 2024
297 days to decisionK233067 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k233067/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 26, 2023
Decision date	Jul 19, 2024
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Chongqing Rob Linka Science and Technology Co., Ltd.
Location	Chongqing, CN
Contact	Huirong Lu
510(k) history	4 submissions · 4 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai CV Technology Co., Ltd.
Contact	Doris Dong

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

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