

K241509 TENS&EMS units (SM9109A, SM9109B)Jun 27, 2024
30 days to decisionK241509 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k241509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	May 28, 2024
Decision date	Jun 27, 2024
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Plexus Yoga, LLC Db a Chirp
Location	Lehi, UT, US
Contact	Jianhua Xu
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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