

**K233364 Axon Therapy**Jan 10, 2024  
100 days to decisionK233364 · Product code: **QPL** · Physical Medicine  
Source: <https://www.510kdatabase.net/k233364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electromagnetic Stimulator, Pain Relief (QPL)
Date received	Oct 2, 2023
Decision date	Jan 10, 2024
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Neuralace Medical, Inc.</b>
Location	San Diego, CA, US
Contact	Joe Milkovits
510(k) history	2 submissions · 2 cleared · 2021-2024

**REGULATORY CONSULTANT**

Consulting firm	<b>RQM+</b>
Contact	Allison Komiyama

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

**CLINICAL EVIDENCE - NCT05620225****Axon Therapy and Conventional Medical Management for Painful Diabetic Neuropathy Compared to Sham and Conventional Medical Management**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	93 patients (actual)
Study sites	7 sites
Condition studied	Neuralgia; Neuropathic Pain; Painful Diabetic Neuropathy
Primary purpose	Treatment
Study type	Interventional
Study design	Crossover
Masking	Triple
Completion date	Nov 22, 2023
Sponsor	NeuraLace Medical, Inc. (Industry)

**Primary outcome**

Comparison of the Proportion of Responders

**Secondary outcome**

Visual Analog Scale (VAS) for Pain

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05620225](https://clinicaltrials.gov/study/NCT05620225)