

K253061 Portable Neuromodulation Stimulator (PoNS)May 13, 2026
233 days to decisionK253061 · Product code: **QCF** · Neurology
Source: <https://www.510kdatabase.net/k253061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrical Tongue Stimulator To Treat Motor Deficits (QCF)
Date received	Sep 22, 2025
Decision date	May 13, 2026
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Helius Medical, Inc.
Location	Newtown, PA, US
Contact	Lawrence Picciano
510(k) history	2 submissions · 1 cleared · 2021-2026

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