

K253536 Evala Nerve Stimulator (EPNR002)Feb 27, 2026
106 days to decisionK253536 · Product code: **ETN** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k253536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Nov 13, 2025
Decision date	Feb 27, 2026
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Epineuron Technologies, Inc.
Location	Mississauga, CA
Contact	Mike Willand
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253536/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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