

K250048 NEUROMARK System (NMK00301)May 29, 2025
139 days to decisionK250048 · Product code: **GEI** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k250048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 10, 2025
Decision date	May 29, 2025
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurent Medical , Ltd.
Location	Galway, IE
Contact	Fay Dalton
Website	https://neuromark.com/
510(k) history	1 submissions · 1 cleared · 2025-2025

Neurent Medical, Ltd. is an innovative medical device company pioneering treatments for chronic inflammatory sino-nasal diseases. Based in Galway, Ireland, the company develops neuromodulation technologies that target hyperactive autonomic nerves to alleviate chronic rhinitis symptoms and improve patient quality of life. Neurent Medical has received FDA 510(k) clearance from total submission. The company specializes exclusively in Ear, Nose, Throat devices, with its first and latest clearance both occurring in 2025. The company remains active, having achieved regulatory c...