

K261833 NEUROMARK System (NMK00301)Jun 16, 2026
14 days to decisionK261833 · Product code: **GEI** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k261833/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Jun 2, 2026 |
| Decision date | Jun 16, 2026 |
| Days to decision | 14 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Neurent Medical , Ltd. |
| Location | Galway, IE |
| Contact | Fay Dalton |
| Website | https://neuromark.com/ |
| 510(k) history | 2 submissions · 2 cleared · 2025-2026 |

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...
