

**K233293 Generation 2.0 Monarch external Trigeminal Nerve Stimulation (eTNS) System®**Jan 16, 2024  
109 days to decisionK233293 · Product code: **QGL** · Neurology  
Source: <https://www.510kdatabase.net/k233293/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcutaneous Nerve Stimulator For Adhd (QGL)
Date received	Sep 29, 2023
Decision date	Jan 16, 2024
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Neurosigma, Inc.</b>
Location	Los Angeles, CA, US
Contact	Colin P. Kealey, M.D.
510(k) history	2 submissions · 1 cleared · 2019-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Blake E. Wilson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233293/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026