FDA 510(k) Premarket Notification

CLEARED

K233293 Generation 2.0 Monarch external Trigeminal Nerve Stimulation (eTNS) System®

Jan 16, 2024
109 days to decision

K233293 · 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	**Neurosigma, Inc.**
Location	Los Angeles, CA, US
Contact	Colin P. Kealey, M.D.
510(k) history	2 submissions · 1 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Blake E. Wilson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov