FDA 510(k) Premarket Notification

K221563 Neurosteer EEG Recorder

CLEARED

Oct 24, 2022
146 days to decision

K221563 · Product code: **OMC** · Neurology
Source: https://www.510kdatabase.net/k221563/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced- Montage Standard Electroencephalograph (OMC)
Date received	May 31, 2022
Decision date	Oct 24, 2022
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neurosteer, Inc.**
Location	New York, NY, US
Contact	Nathan Intrator
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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