FDA 510(k) Premarket Notification

K232688 NQ TMS for MDD (NQv1-MU-01)

CLEARED

Dec 29, 2023
119 days to decision

K232688 · Product code: **OBP** · Neurology
Source: https://www.510kdatabase.net/k232688/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Sep 1, 2023
Decision date	Dec 29, 2023
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuroqore, Inc.**
Location	San Francisco, CA, US
Contact	Mehran Talebinejad
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Makromed, Inc.**
Contact	Barry Ashar

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