FDA 510(k) Premarket Notification

K243319 Ampa One System (AMPA-001)

CLEARED

Feb 13, 2025
113 days to decision

K243319 · Product code: **OBP** · Neurology
Source: https://www.510kdatabase.net/k243319/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Oct 23, 2024
Decision date	Feb 13, 2025
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuromodulatory Devices & Applications**
Location	San Diego, CA, US
Contact	Don Vaughn
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Avio Medtech Consulting**
Contact	Tyler Ting

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