FDA 510(k) Premarket Notification

CLEARED

K231926 NeuroStar Advanced Therapy System (All previously cleared models)

Mar 22, 2024
266 days to decision

K231926 · Product code: **OBP** · Neurology
Source: https://www.510kdatabase.net/k231926/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Jun 30, 2023
Decision date	Mar 22, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuronetics, Inc.**
Location	Malvern, PA, US
Contact	Robin Fatzinger
Website	http://www.neuronetics.com
510(k) history	8 submissions · 8 cleared · 2016-2024

Neuronetics, Inc. develops non-invasive neurology devices for treating psychiatric and neurological disorders. The company specializes in transcranial magnetic stimulation (TMS) therapy systems, with a manufacturing facility in Malvern, US. Neuronetics has received FDA 510(k) clearances from total submissions since its first clearance in 2016. All submissions focus on neurology devices. The company remains actively engaged in regulatory submissions, with its latest clearance in 2024. The company's primary product platform is NeuroStar Advanced Therapy System, indicated fo...