CLEARED

K220127 NeuroStar TMS Therapy System, NeuroStar Advanced Therapy System, NeuroStar, NeuroStar Advanced Therapy for Mental Health

Jul 15, 2022
178 days to decision

K220127 · Product code: **OBP** · Neurology
Source: https://www.510kdatabase.net/k220127/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Jan 18, 2022
Decision date	Jul 15, 2022
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuronetics, Inc.**
Location	Malvern, PA, US
Contact	Cory Anderson
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...