FDA 510(k) Premarket Notification

CLEARED

K222230 NeuroStar, NeuroStar TMS Therapy System, NeuroStar Advanced Therapy System, NeuroStar Advanced Therapy System for Mental Health

Aug 24, 2022
30 days to decision

K222230 · Product code: **OBP** · Neurology
Source: https://www.510kdatabase.net/k222230/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Jul 25, 2022
Decision date	Aug 24, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuronetics, Inc.**
Location	Malvern, PA, US
Contact	Amanda Pentecost
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...