FDA 510(k) Premarket Notification

K130233 NEUROSTAR TMS THERAPY SYSTEM

CLEARED

Apr 30, 2013
90 days to decision

K130233 · Product code: **OBP** · Neurology
Source: https://www.510kdatabase.net/k130233/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Jan 30, 2013
Decision date	Apr 30, 2013
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neuronetics**
Location	Malvern, PA, US
Contact	JUDY P WAYS, PH.D.
Website	http://www.neuronetics.com
510(k) history	7 submissions · 6 cleared · 2008-2023

Neuronetics 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 2008. All submissions focused on neurology devices. The company's regulatory activity concluded in 2023, making this a historical record of its FDA clearance history. The company's primary product is the NeuroStar Advanced Therapy System, a TMS...