FDA 510(k) Premarket Notification

K160703 NeuroStar TMS Therapy System

CLEARED

Jun 10, 2016
88 days to decision

K160703 · Product code: **OBP** · Neurology
Source: https://www.510kdatabase.net/k160703/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Mar 14, 2016
Decision date	Jun 10, 2016
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neuronetics, Inc.**
Location	Malvern, PA, US
Contact	Judy P. Ways
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...