CLEARED

May 6, 2022
289 days to decision

K212289 NeuroStar Advanced Therapy for adjunctive treatment of OCD, NeuroStar Advanced Therapy System, NeuroStar TMS Therapy System, NeuroStar Advanced Therapy for Mental Health, NeuroStar

K212289 · Product code: **QCI** · Neurology
Source: https://www.510kdatabase.net/k212289/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulation System For Obsessive-compulsive Disorder (QCI)
Date received	Jul 21, 2021
Decision date	May 6, 2022
Days to decision	289 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...