

K231350 OCD MT Cap (85-00397-000)Jun 8, 2023
30 days to decisionK231350 · Product code: **QCI** · Neurology
Source: <https://www.510kdatabase.net/k231350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transcranial Magnetic Stimulation System For Obsessive-compulsive Disorder (QCI)
Date received	May 9, 2023
Decision date	Jun 8, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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