

**K201158 NeuroStar Advanced Therapy**Nov 20, 2020  
204 days to decisionK201158 · Product code: **OBP** · Neurology  
Source: <https://www.510kdatabase.net/k201158/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Apr 30, 2020
Decision date	Nov 20, 2020
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neuronetics, Inc.</b>
Location	Malvern, PA, US
Contact	Gary Johnson
Website	<a href="http://www.neuronetics.com">http://www.neuronetics.com</a>
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...

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