

**K222196 Deep TMS System**May 31, 2024  
679 days to decisionK222196 · Product code: **OBP** · Neurology  
Source: <https://www.510kdatabase.net/k222196/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Jul 22, 2022
Decision date	May 31, 2024
Days to decision	679 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brainsway , Ltd.</b>
Location	Kfar Saba, IL
Contact	Ahava Stein
510(k) history	11 submissions · 11 cleared · 2013-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>A. Stein - Regulatory Affairs Consulting , Ltd.</b>
Contact	Ahava Stein

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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