

K210201 Deep Transcranial Magnetic Stimulation (DTMS) System

Aug 17, 2021
204 days to decisionK210201 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k210201/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Jan 25, 2021
Decision date	Aug 17, 2021
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	A. Stein-Regulator Affairs Consulting , Ltd.
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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210201/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026