

K203735 Brainsway Deep TMS System

Apr 23, 2021
123 days to decisionK203735 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k203735/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Dec 21, 2020
Decision date	Apr 23, 2021
Days to decision	123 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 - Regulatory 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

CLINICAL EVIDENCE - NCT04679753

Brainsway DTMS for Treatment of MDD Using iTBS

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	177 patients (actual)
Study sites	1 site
Condition studied	Major Depressive Disorder
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jul 1, 2020
Sponsor	Brainsway (Industry)

Primary outcome

The primary outcome measure was the change from baseline in HDRS-21 scores at the 5 week visit.

Secondary outcome

HDRS-21 Response and Remission rates

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04679753