FDA 510(k) Premarket Notification

CLEARED

K220819 BrainsWay Deep TMS System

Aug 26, 2022
158 days to decision

K220819 · Product code: **OBP** · Neurology
Source: https://www.510kdatabase.net/k220819/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Mar 21, 2022
Decision date	Aug 26, 2022
Days to decision	158 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 - NCT03012724

Efficacy of H7-Coil DTMS Compared to H1-Coil DTMS in Subjects With Major Depression Disorder (MDD)

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	106 patients (estimated)
Study sites	9 sites
Condition studied	Major Depressive Disorder (MDD)
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Dec 1, 2020
Sponsor	Brainsway (Industry)

Primary outcome

HDRS-21 Score Change From Baseline

Secondary outcome

Response Rate in HDRS-21

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03012724