FDA 510(k) Premarket Notification

CLEARED

K210201 Deep Transcranial Magnetic Stimulation (DTMS) System

Aug 17, 2021
204 days to decision

K210201 · 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-Regulatort 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