FDA 510(k) Premarket Notification

K203616 Brainsway Deep (DTMS) System

CLEARED

Apr 16, 2021
127 days to decision

K203616 · Product code: **QMD** · Neurology
Source: https://www.510kdatabase.net/k203616/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulation System For Smoking Cessation (QMD)
Date received	Dec 10, 2020
Decision date	Apr 16, 2021
Days to decision	127 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