

K251391 BrainsWay Deep TMS SystemNov 7, 2025
186 days to decisionK251391 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k251391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	May 5, 2025
Decision date	Nov 7, 2025
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Brainsway , Ltd.
Location	Kfar Saba, IL
Contact	Colleen Hanlon
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

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