

**K203616 Brainsway Deep (DTMS) System**Apr 16, 2021  
127 days to decisionK203616 · Product code: **QMD** · Neurology  
Source: <https://www.510kdatabase.net/k203616/>**SUBMISSION DETAILS**

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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**

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Company	<b>Brainsway , Ltd.</b>
Location	Kfar Saba, IL
Contact	Ahava Stein
510(k) history	11 submissions · 11 cleared · 2013-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>A. Stein Regulatory Affairs Consulting , Ltd.</b>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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