

K183303 Brainsway Deep TMS SystemMar 8, 2019
101 days to decisionK183303 · Product code: **QCI** · Neurology
Source: <https://www.510kdatabase.net/k183303/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transcranial Magnetic Stimulation System For Obsessive-compulsive Disorder (QCI) |
| Date received | Nov 27, 2018 |
| Decision date | Mar 8, 2019 |
| Days to decision | 101 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Brainsway , Ltd. |
| Location | Kfar Saba, IL |
| Contact | Moria Ankri |
| 510(k) history | 11 submissions · 11 cleared · 2013-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183303/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026