

**K243460 Ultimate rTMS**Apr 17, 2025  
160 days to decisionK243460 · Product code: **OBP** · Neurology  
Source: <https://www.510kdatabase.net/k243460/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Nov 8, 2024
Decision date	Apr 17, 2025
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brain Ultimate, Inc.</b>
Location	Alpharetta, GA, US
Contact	Frank Ge
510(k) history	3 submissions · 3 cleared · 2023-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Makromed, Inc.</b>
Contact	Barry Ashar

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/k243460/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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