

K230735 Ultimate rTMSSep 13, 2023
181 days to decisionK230735 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k230735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Mar 16, 2023
Decision date	Sep 13, 2023
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Yingchi rTMS

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Makromed, Inc.
Contact	Barry Ashar

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230735/> 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