

K243459 Ultimate rTMS for OCD (M-series)Apr 17, 2025
160 days to decisionK243459 · Product code: **QCI** · Neurology
Source: <https://www.510kdatabase.net/k243459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulation System For Obsessive-compulsive Disorder (QCI)
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

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

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