FDA 510(k) Premarket Notification

K260402 MeRT System

CLEARED

Jun 3, 2026
117 days to decision

K260402 · Product code: **QCI** · Neurology
Source: https://www.510kdatabase.net/k260402/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulation System For Obsessive-compulsive Disorder (QCI)
Date received	Feb 6, 2026
Decision date	Jun 3, 2026
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wave Neuroscience**
Location	Newport Beach, CA, US
Contact	Leslie Prichep
510(k) history	1 submissions · 1 cleared · 2026-2026

CLINICAL EVIDENCE - NCT02990793

Clinical Trial to Evaluate the Safety and Efficacy of MeRT Treatment in Post-Traumatic Stress Disorder

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	158 patients (actual)
Study sites	8 sites
Condition studied	PostTraumatic Stress Disorder; Traumatic Brain Injury; Postconcussive Symptoms
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Nov 4, 2025
Sponsor	Wave Neuroscience (Industry)

Primary outcome

Change in PTSD Symptoms

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02990793