

K261471 Zeta TMS Navigation System

Jul 9, 2026
66 days to decision

K261471 · Product code: QFF · Neurology
Source: <https://www.510kdatabase.net/k261471/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electromechanical Arm For A Transcranial Magnetic Stimulation System (QFF)
Date received	May 4, 2026
Decision date	Jul 9, 2026
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zeta Surgical, Inc.
Location	Boston, MA, US
Contact	Hieu Le Mau
Website	https://www.zetasurgical.com
510(k) history	5 submissions · 5 cleared · 2024-2026

Zeta Surgical, Inc. develops AI-powered neuronavigation systems for brain surgery and neuromodulation. The company operates with a manufacturing facility in Boston, US. Their platform delivers real-time, frameless image-guided navigation with submillimeter accuracy across operating rooms, emergency settings, and ambulatory centers. Zeta Surgical has received FDA 510(k) clearances from total submissions since 2024. The company specializes exclusively in Neurology devices, with its most recent clearance in 2026. All submissions have resulted in clearances, demonstrating a s...