

K251927 Zeta Navigation System (ZNS131-US)Oct 10, 2025
109 days to decisionK251927 · Product code: **SGE** · Neurology
Source: <https://www.510kdatabase.net/k251927/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Extracranial Positional System For A Transcranial Magnetic Stimulation System (SGE)
Date received	Jun 23, 2025
Decision date	Oct 10, 2025
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	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	4 submissions · 4 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...