

## K253663 Zeta Navigation System

May 1, 2026  
162 days to decisionK253663 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k253663/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Nov 20, 2025
Decision date	May 1, 2026
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Zeta Surgical, Inc.</b>
Location	Boston, MA, US
Contact	Hieu Le Mau
Website	<a href="https://www.zetasurgical.com">https://www.zetasurgical.com</a>
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...