

K233903 Zeta Cranial Navigation System (ZNS131-US)Jan 10, 2024
30 days to decisionK233903 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k233903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Dec 11, 2023
Decision date	Jan 10, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zeta Surgical, Inc.
Location	Boston, MA, US
Contact	Roman Stolyarov
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...