

**K230661 Zeta Cranial Navigation System**Sep 8, 2023  
182 days to decisionK230661 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k230661/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Neurological Stereotaxic Instrument (HAW) |
| Date received         | Mar 10, 2023                              |
| Decision date         | Sep 8, 2023                               |
| Days to decision      | 182 days                                  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Zeta Surgical</b>                  |
| Location       | Boston, MA, US                        |
| Contact        | Jose Amich                            |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230661/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026