

K954789 BRAINLAB HEADPINSAug 12, 1996
299 days to decisionK954789 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k954789/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Neurological Stereotaxic Instrument (HAW) |
| Date received | Oct 18, 1995 |
| Decision date | Aug 12, 1996 |
| Days to decision | 299 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Brainlab AG |
| Location | Heimstetten, DE |
| Contact | STEFAN LIP[PSTREU |
| Website | http://brainlab.com |
| 510(k) history | 135 submissions · 135 cleared · 1996-2025 |

Brainlab AG is a digital medical technology company specializing in image-guided surgery and neurology devices. The company operates with a manufacturing facility in Heimstetten, Germany, and develops innovative surgical navigation and alignment systems for cranial, spine, and neurosurgical procedures. Brainlab has received FDA 510(k) clearances from total submissions since its first clearance in 1996. The company maintains a strong regulatory presence in neurology devices, with recent clearances spanning surgical navigation systems, robotic alignment platforms, trajector...
