

K042543 IPLAN! DIGITAL TEMPLATINGMay 17, 2005
239 days to decisionK042543 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k042543/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Neurological Stereotaxic Instrument (HAW) |
| Date received | Sep 20, 2004 |
| Decision date | May 17, 2005 |
| Days to decision | 239 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Brainlab AG |
| Location | Heimstetten, DE |
| Contact | RAINER BIRKENBACH |
| 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...
