

**K020631 IPLAN**Sep 9, 2002  
194 days to decisionK020631 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k020631/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Neurological Stereotaxic Instrument (HAW) |
| Date received         | Feb 27, 2002                              |
| Decision date         | Sep 9, 2002                               |
| Days to decision      | 194 days                                  |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Brainlab AG</b>                                    |
| Location       | Heimstetten, DE                                       |
| Contact        | RAINER BIRKENBACH                                     |
| Website        | <a href="http://brainlab.com">http://brainlab.com</a> |
| 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...

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