

K983410 @ TARGETSep 17, 1999
354 days to decisionK983410 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k983410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 28, 1998
Decision date	Sep 17, 1999
Days to decision	354 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Brainlab AG
Location	Heimstetten, DE
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...

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Device record: <https://www.510kdatabase.net/k983410/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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