

K101627 IPLANJun 3, 2011
359 days to decisionK101627 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k101627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jun 9, 2010
Decision date	Jun 3, 2011
Days to decision	359 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Brainlab AG
Location	Heimstetten, DE
Contact	ALEXANDER SCHWIERSCH
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...
