

**K010602 VECTORVISION HIP**Sep 12, 2001  
196 days to decisionK010602 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k010602/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Feb 28, 2001
Decision date	Sep 12, 2001
Days to decision	196 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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