

**K122225 STERILE RADIOLUCENT SKULL PINS**

Apr 26, 2013  
275 days to decision

K122225 · Product code: **HBL** · Neurology  
Source: <https://www.510kdatabase.net/k122225/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holder, Head, Neurosurgical (skull Clamp) (HBL)
Date received	Jul 25, 2012
Decision date	Apr 26, 2013
Days to decision	275 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brainlab AG</b>
Location	Heimstetten, DE
Contact	ALEXANDER SCHWIERSCH
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...