

**K053500 FRAMELESS RADIOSURGERY COMPONENTS**Feb 3, 2006  
49 days to decisionK053500 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k053500/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 16, 2005
Decision date	Feb 3, 2006
Days to decision	49 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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