

**K202050 Cranial 4Pi Immobilization**Aug 19, 2020  
26 days to decisionK202050 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k202050/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 24, 2020
Decision date	Aug 19, 2020
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brainlab AG</b>
Location	Heimstetten, DE
Contact	Chiara Cunico
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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