

**K243633 Brainlab Elements (7.0)**Jun 13, 2025  
200 days to decisionK243633 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k243633/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 25, 2024
Decision date	Jun 13, 2025
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Brainlab Elements Image Fusion (5.0); Brainlab Elements Image Fusion Angio (1.0); Brainlab Elements Contouring (5.0); Brainlab Elements Fibertracking (3.0); Brainlab Elements BOLD MRI Mapping (1.0)

**APPLICANT**

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Company	<b>Brainlab AG</b>
Location	Heimstetten, DE
Contact	Sadwini Suresh
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...