

**K250440 RT Elements (4.5)**Jun 17, 2025  
123 days to decisionK250440 · Product code: **MUJ** · Radiology  
Source: <https://www.510kdatabase.net/k250440/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Feb 14, 2025
Decision date	Jun 17, 2025
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	(Elements) Multiple Brain Mets SRS; (Elements) Cranial SRS; (Elements) Spine SRS; (Elements) Cranial SRS w/ Cones; (Elements) RT Planning Platform; (Elements) Dose Review; (Elements) Retreatment Review; Elements Segmentation [Cranial , Basal Ganglia, Head & Neck, Pelvic, Spine, Thoracic & Spine, Extracranial] RT; Elements AI Tumor Segmentation RT; Elements SmartBrush [Angio, Spine] RT; Elements Object Management RT

**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...