

K190664 RT Elements, Cranial SRS, Spine SRS, Multiple Brain Mets SRS, RT QA, Adaptive Hybrid Surgery Analysis, Dose Review

Apr 12, 2019
28 days to decision

K190664 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k190664/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Mar 15, 2019
Decision date	Apr 12, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Brainlab AG
Location	Heimstetten, DE
Contact	Rainer Birkenbach
Website	http://brainlab.com
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...