FDA 510(k) Premarket Notification

K223279 RT Elements (4.0)

CLEARED

Mar 14, 2023
141 days to decision

K223279 · Product code: **MUJ** · Radiology
Source: https://www.510kdatabase.net/k223279/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Oct 24, 2022
Decision date	Mar 14, 2023
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brainlab AG**
Location	Heimstetten, DE
Contact	Sadwini Suresh
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...