FDA 510(k) Premarket Notification

K080888 MODEIFICATION TO IPLAN RT DOSE

CLEARED

Jun 11, 2008
72 days to decision

K080888 · Product code: **MUJ** · Radiology
Source: https://www.510kdatabase.net/k080888/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Mar 31, 2008
Decision date	Jun 11, 2008
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Brainlab AG**
Location	Heimstetten, DE
Contact	CARSTEN RAUPACH
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...