K113732 IPLAN (IPLAN CRANIAL, IPLAN STEREOTAXY, IPLAN ENT, IPLAN CMF, IPLAN VIEW, IPLAN SPINE)

CLEARED

May 7, 2012
140 days to decision

K113732 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k113732/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Dec 19, 2011
Decision date	May 7, 2012
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Brainlab AG**
Location	Heimstetten, DE
Contact	ALEXANDER SCHWIERSCH
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...