

K201276 ExacTrac DynamicJul 13, 2020
61 days to decisionK201276 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k201276/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	May 13, 2020
Decision date	Jul 13, 2020
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Brainlab AG
Location	Heimstetten, DE
Contact	Chiara Cunico
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...
