

K170816 Elements Image Fusion, Elements Cranial Distortion Correction, Elements Spine Curvature Correction, Elements TRAM

Sep 26, 2017
190 days to decision

K170816 · Product code: LLZ · Radiology
Source: <https://www.510kdatabase.net/k170816/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 20, 2017
Decision date	Sep 26, 2017
Days to decision	190 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...