

# K212245 Spine and Trauma Navigation System, Spine & Trauma 3D Navigation, Instrument Selection, Fluoro 3D, Registration Software Fluoro 3D, Registration Software Paired Point, Registration Software Spine Surface Matching, Spine Planning, Elements Screw Planning Spine, Elements Spine Screw Planning

Apr 13, 2022  
268 days to decision

K212245 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k212245/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jul 19, 2021
Decision date	Apr 13, 2022
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Brainlab AG</b>
Location	Heimstetten, DE
Contact	Chiara Cunico
Website	<a href="http://brainlab.com">http://brainlab.com</a>
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...