

K221618 Spine & Trauma Navigation, Spine Navigation, Navigation Software Spine & Trauma, Alignment System Spine, Alignment Software Spine, Cirq Arm System

Aug 30, 2022
88 days to decision

K221618 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k221618/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 3, 2022
Decision date	Aug 30, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	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...