

K202320 CIRQ Robotic Alignment Module, Cirq, Cirq Robotic Alignment Module Spinal, Cirq Robotic Alignment Cranial and Spine, CIRQ Robotic Alignment Cranial and Spine System

Dec 23, 2020
128 days to decision

K202320 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k202320/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Aug 17, 2020
Decision date	Dec 23, 2020
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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