

K243698 Alignment System Cranial, with Alignment Software Cranial with LITT

Jan 28, 2025
60 days to decisionK243698 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k243698/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Nov 29, 2024
Decision date	Jan 28, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Cirq Alignment Software Cranial Biopsy; Cirq Alignment Software Cranial sEEG; VarioGuide Alignment Software Cranial; Cirq Alignment Software Cranial LITT

APPLICANT

Company	Brainlab AG
Location	Heimstetten, DE
Contact	Esther Moreno Garcia
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...