

K240701 Drill GuideMay 23, 2024
70 days to decisionK240701 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k240701/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Mar 14, 2024
Decision date	May 23, 2024
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Drill Bit; Spine & Trauma Navigation

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...

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