FDA 510(k) Premarket Notification

# K203679 Automatic Registration

**CLEARED**

Mar 18, 2021
91 days to decision

K203679 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k203679/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | Dec 17, 2020 |
| Decision date | Mar 18, 2021 |
| Days to decision | 91 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...