CLEARED

Oct 8, 2020
377 days to decision

K192703 Cranial Image Guided Surgery System, Navigation Software Cranial, Navigation Software ENT, Registration Software Cranial, Automatic Registration 2.0, Ultrasound Navigation Software (BK), Intraoperative Structure Update

K192703 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k192703/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 27, 2019
Decision date	Oct 8, 2020
Days to decision	377 days
Third-party review	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...