

**K231498 TraumaCad Neo**Nov 20, 2023  
180 days to decisionK231498 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k231498/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 24, 2023
Decision date	Nov 20, 2023
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brainlab , Ltd.</b>
Location	Petach-Tikva, IL
Contact	Yael Guttentag
Website	<a href="https://www.brainlab.com/">https://www.brainlab.com/</a>
510(k) history	2 submissions · 2 cleared · 2023-2025

Brainlab, Ltd. is a medical device company specializing in digital medical technologies for improved patient outcomes. The company operates with a manufacturing facility in Petach-Tikva, IL. Brainlab has received FDA 510(k) clearances from total submissions. The company's regulatory focus is entirely on Radiology devices. First clearance was achieved in 2023, with the most recent clearance in 2025, demonstrating continued active development and FDA engagement. The company's cleared portfolio includes advanced imaging and surgical planning solutions within the Radiology ca...