FDA 510(k) Premarket Notification

K243810 TraumaCad Neo (1.1)

CLEARED

Jun 4, 2025
175 days to decision

K243810 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k243810/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 11, 2024
Decision date	Jun 4, 2025
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brainlab , Ltd.**
Location	Petach-Tikva, IL
Contact	Veronika Kravtsov
Website	https://www.brainlab.com/
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...