FDA 510(k) Premarket Notification

K243681 Neuro Insight V1.0

CLEARED

Jul 23, 2025
236 days to decision

K243681 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k243681/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 29, 2024
Decision date	Jul 23, 2025
Days to decision	236 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Olea Medical S.A.S.**
Location	La Ciotat, FR
Contact	Nathalie Palumbo
510(k) history	3 submissions · 3 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov