FDA 510(k) Premarket Notification

CLEARED

K223532 Olea S.I.A. Neurovascular V1.0

Jun 6, 2023
195 days to decision

K223532 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k223532/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 23, 2022
Decision date	Jun 6, 2023
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Olea Medical**
Location	Austin, TX, US
Contact	Nathalie Palumbo
510(k) history	11 submissions · 11 cleared · 2009-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov