FDA 510(k) Premarket Notification

K223091 CT Perfusion V1.0

CLEARED

Jun 9, 2023
252 days to decision

K223091 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k223091/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 30, 2022
Decision date	Jun 9, 2023
Days to decision	252 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**
Contact	John J Smith

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