

K223091 CT Perfusion V1.0Jun 9, 2023
252 days to decisionK223091 · 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](https://accessdata.fda.gov)

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