

K223502 MR Diffusion Perfusion Mismatch V1.0Jan 13, 2023
53 days to decisionK223502 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k223502/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 21, 2022
Decision date	Jan 13, 2023
Days to decision	53 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.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223502/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026