

K230552 MR DWI/FLAIR Measurement V1.0Apr 26, 2023
57 days to decisionK230552 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k230552/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 28, 2023
Decision date	Apr 26, 2023
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230552/> 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