

**K221426 Functional MR V1.0**Jul 6, 2022  
51 days to decisionK221426 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k221426/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 16, 2022
Decision date	Jul 6, 2022
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olea Medical S.A.S.</b>
Location	La Ciotat, FR
Contact	Nathalie Palumbo
510(k) history	3 submissions · 3 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
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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