

K132095 OLEA SPHEREDec 26, 2013
171 days to decisionK132095 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k132095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 8, 2013
Decision date	Dec 26, 2013
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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