

**K191125 ADAS 3D**Jan 15, 2020  
261 days to decisionK191125 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k191125/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 29, 2019
Decision date	Jan 15, 2020
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Galgo Medical S.L</b>
Location	Barcelona, ES
Contact	Antoni Riu
510(k) history	1 submissions · 1 cleared · 2020-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191125/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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