

**K261352 2D Hip Planning Software**Jun 8, 2026  
45 days to decisionK261352 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k261352/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 24, 2026
Decision date	Jun 8, 2026
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>One Ortho</b>
Location	Saint-Genis-Laval, FR
Contact	Theo Vidal
510(k) history	1 submissions · 1 cleared · 2026-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261352/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 11, 2026