

**K251022 3D-SHAPER**Sep 5, 2025  
156 days to decisionK251022 · Product code: **KGI** · Radiology  
Source: <https://www.510kdatabase.net/k251022/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometer, Bone (KGI)
Date received	Apr 2, 2025
Decision date	Sep 5, 2025
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3D-Shaper Medical S.L</b>
Location	Barcelona, ES
Contact	Ludovic Humbert
510(k) history	2 submissions · 2 cleared · 2022-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251022/> 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 May 13, 2026