

**K252443 SpaceFix Shoulder Spacer**Sep 15, 2025  
42 days to decisionK252443 · Product code: **MBB** · Orthopedic  
Source: <https://www.510kdatabase.net/k252443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Antibiotic (MBB)
Date received	Aug 4, 2025
Decision date	Sep 15, 2025
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>G21, S.R.L.</b>
Location	San Possidonio, IT
Contact	Filippo Foroni
510(k) history	12 submissions · 12 cleared · 2015-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQMIS, Inc.</b>
Contact	Barry Sands

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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