

K252326 InterSpace GV Hip SpacerAug 6, 2025
12 days to decisionK252326 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k252326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Jul 25, 2025
Decision date	Aug 6, 2025
Days to decision	12 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tecres S.P.A.
Location	Bethesda, MD, US
Contact	Giuseppe Gazzara
510(k) history	14 submissions · 14 cleared · 2005-2025

REGULATORY CONSULTANT

Consulting firm	MCRA
Contact	Michael Coladonato

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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