

K253675 OsteoRemedies Hip Spacer SystemDec 23, 2025
32 days to decisionK253675 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k253675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Nov 21, 2025
Decision date	Dec 23, 2025
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osteoremedies, LLC
Location	Memphis, TN, US
Contact	Eric Stookey
Website	https://osteoremedies.com
510(k) history	11 submissions · 11 cleared · 2015-2025

Osteoremedies, LLC is a Memphis, Tennessee-based medical device manufacturer specializing in orthopedic solutions for complex surgical infections and joint reconstruction. The company develops spacer systems, bone cements, and surgical adjuncts designed for infection management and revision procedures. Osteoremedies has received FDA 510(k) clearances from total submissions since its first clearance in 2015. All submissions have focused on orthopedic devices. The company remains actively engaged in regulatory submissions, with its most recent clearance in 2025. The company...

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Hollace Saas Rhodes

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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Device record: <https://www.510kdatabase.net/k253675/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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