

**K192995 OsteoRemedies Hip Spacer System**Jan 10, 2020  
77 days to decisionK192995 · Product code: **KWL** · Orthopedic  
Source: <https://www.510kdatabase.net/k192995/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Oct 25, 2019
Decision date	Jan 10, 2020
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osteoremedies, LLC</b>
Location	Memphis, TN, US
Contact	Eric Stookey
Website	<a href="https://osteoremedies.com">https://osteoremedies.com</a>
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...

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