

**K152267 Remedy® Shoulder Spacer**Dec 15, 2015  
126 days to decisionK152267 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k152267/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Aug 11, 2015
Decision date	Dec 15, 2015
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Osteoremedies, LLC</b>
Location	Memphis, TN, US
Contact	Chris Hughes
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...

---