

K172906 REMEDY PLUS Hip Spacer, UNITE PLUS Bone CementAug 29, 2018
341 days to decisionK172906 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k172906/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Sep 22, 2017
Decision date	Aug 29, 2018
Days to decision	341 days
Third-party review	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...
