

K191981 REMEDY Acetabular CupAug 23, 2019
30 days to decisionK191981 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k191981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Jul 24, 2019
Decision date	Aug 23, 2019
Days to decision	30 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...
