FDA 510(k) Premarket Notification

CLEARED

K242377 REMEDY Stemmed Knee Spacer System with All-Poly Tibial Component

Oct 2, 2024
54 days to decision

K242377 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k242377/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Aug 9, 2024
Decision date	Oct 2, 2024
Days to decision	54 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	Michael Coladonato

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov