FDA 510(k) Premarket Notification

K223650 REMEDY Stemmed Knee Spacer

CLEARED

Jan 5, 2023
30 days to decision

K223650 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k223650/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 6, 2022
Decision date	Jan 5, 2023
Days to decision	30 days
Third-party review	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	Hollace Rhodes

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