FDA 510(k) Premarket Notification

CLEARED

K243991 Klassic Knee System - Revision Tibial Baseplate

Mar 24, 2025
88 days to decision

K243991 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k243991/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 26, 2024
Decision date	Mar 24, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Total Joint Othopedics, Inc.**
Location	Salt Lake City, UT, US
Contact	Bobbi Siddoway
510(k) history	8 submissions · 8 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	**Arthroplasty Regulatory Consulting**
Contact	Chris Weaber

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