FDA 510(k) Premarket Notification

K230537 Klassic Knee Revision System

CLEARED

May 19, 2023
81 days to decision

K230537 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k230537/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Feb 27, 2023
Decision date	May 19, 2023
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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