FDA 510(k) Premarket Notification

CLEARED

K231253 Overture Orthopaedics Patellofemoral System

Jul 7, 2023
67 days to decision

K231253 · Product code: **KRR** · Orthopedic
Source: https://www.510kdatabase.net/k231253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femoral, Semi-constrained, Cemented, Metal/polymer (KRR)
Date received	May 1, 2023
Decision date	Jul 7, 2023
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Overture Resurfacing, Inc.**
Location	New York, NY, US
Contact	Riley Williams
510(k) history	2 submissions · 2 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Cor Medical Ventures, Inc.**
Contact	Benjamin Arnold

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