FDA 510(k) Premarket Notification

K230180 Rosa Knee System

CLEARED

Feb 22, 2023
30 days to decision

K230180 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k230180/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 23, 2023
Decision date	Feb 22, 2023
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthosoft Inc. (d/b/a) Zimmer CAS**
Location	Montreal, CA
Contact	Kruti Gosalia
Website	https://www.zimmerbiomet.com
510(k) history	18 submissions · 18 cleared · 2017-2026