FDA 510(k) Premarket Notification

K230243 ROSA® Knee System

CLEARED

Mar 29, 2023
58 days to decision

K230243 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k230243/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 30, 2023
Decision date	Mar 29, 2023
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orthosoft D/B/A Zimmer Cas**
Location	Montreal, CA
Contact	Aura Helena Corredor
510(k) history	7 submissions · 7 cleared · 2021-2023