

K230243 ROSA® Knee SystemMar 29, 2023
58 days to decisionK230243 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230243/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026