

**K251314 Rosa® Knee System**Nov 13, 2025  
199 days to decisionK251314 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k251314/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 28, 2025
Decision date	Nov 13, 2025
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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