

K260582 ROSA® Shoulder SystemMay 21, 2026
90 days to decisionK260582 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k260582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Feb 20, 2026
Decision date	May 21, 2026
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Orthosoft Inc. (d/b/a) Zimmer CAS
Location	Montreal, CA
Contact	Viviana Hernandez
Website	https://www.zimmerbiomet.com
510(k) history	19 submissions · 19 cleared · 2017-2026

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