

K213708 ROSA® Knee SystemApr 22, 2022
149 days to decisionK213708 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k213708/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 24, 2021
Decision date	Apr 22, 2022
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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