

K232425 Signature™ ONE SystemDec 12, 2023
123 days to decisionK232425 · Product code: **QHE** · Orthopedic
Source: <https://www.510kdatabase.net/k232425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Aug 11, 2023
Decision date	Dec 12, 2023
Days to decision	123 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	Nilam Dave
Website	https://www.zimmerbiomet.com
510(k) history	18 submissions · 18 cleared · 2017-2026

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