

K260104 Signature™ ONE SystemFeb 4, 2026
22 days to decisionK260104 · Product code: **QHE** · Orthopedic
Source: <https://www.510kdatabase.net/k260104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Jan 13, 2026
Decision date	Feb 4, 2026
Days to decision	22 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260104/> 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 13, 2026