

K261510 Signature™ ONE SystemJun 4, 2026
28 days to decisionK261510 · Product code: **QHE** · Orthopedic
Source: <https://www.510kdatabase.net/k261510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	May 7, 2026
Decision date	Jun 4, 2026
Days to decision	28 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	Camilo Aranguren
Website	https://www.zimmerbiomet.com
510(k) history	20 submissions · 20 cleared · 2017-2026

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