FDA 510(k) Premarket Notification

K260104 Signature™ ONE System

CLEARED

Feb 4, 2026
22 days to decision

K260104 · 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