

**K212560 Signature™ ONE System**Oct 12, 2021  
60 days to decisionK212560 · Product code: **QHE** · Orthopedic  
Source: <https://www.510kdatabase.net/k212560/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Aug 13, 2021
Decision date	Oct 12, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Orthosoft Inc. (d/b/a) Zimmer CAS</b>
Location	Montreal, CA
Contact	Sankalp Dere
Website	<a href="https://www.zimmerbiomet.com">https://www.zimmerbiomet.com</a>
510(k) history	18 submissions · 18 cleared · 2017-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212560/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026