

K190595 Signature ONE SystemJun 5, 2019
90 days to decisionK190595 · Product code: **KWT** · Orthopedic
Source: <https://www.510kdatabase.net/k190595/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT) |
| Date received | Mar 7, 2019 |
| Decision date | Jun 5, 2019 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Orthosoft Inc. (d/b/a) Zimmer CAS |
| Location | Montreal, CA |
| Contact | Paul Hardy |
| Website | https://www.zimmerbiomet.com |
| 510(k) history | 18 submissions · 18 cleared · 2017-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190595/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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