

K192074 Signature ONE SystemAug 30, 2019
28 days to decisionK192074 · Product code: **QHE** · Orthopedic
Source: <https://www.510kdatabase.net/k192074/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Aug 2, 2019
Decision date	Aug 30, 2019
Days to decision	28 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

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