FDA 510(k) Premarket Notification

K212560 Signature™ ONE System

CLEARED

Oct 12, 2021
60 days to decision

K212560 · 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	**Orthosoft Inc. (d/b/a) Zimmer CAS**
Location	Montreal, CA
Contact	Sankalp Dere
Website	https://www.zimmerbiomet.com
510(k) history	18 submissions · 18 cleared · 2017-2026