FDA 510(k) Premarket Notification

K202232 Comprehensive Vault Reconstruction System

CLEARED

Feb 19, 2021
196 days to decision

K202232 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k202232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Aug 7, 2020
Decision date	Feb 19, 2021
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Manufacturing Corp**
Location	Warsaw, IN, US
Contact	Patricia Sandborn Beres
510(k) history	93 submissions · 93 cleared · 2004-2023