K214001 Comprehensive® Shoulder System, Comprehensive® Reverse Shoulder System

CLEARED

Mar 15, 2023
449 days to decision

K214001 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k214001/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Dec 21, 2021
Decision date	Mar 15, 2023
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k214001/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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