

K181611 Comprehensive Reverse Shoulder SystemSep 24, 2018
97 days to decisionK181611 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k181611/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Jun 19, 2018
Decision date	Sep 24, 2018
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181611/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026