

K212800 PRIMA Humeral System and SMR Glenosphere Ø42Feb 25, 2022
176 days to decisionK212800 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k212800/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Sep 2, 2021
Decision date	Feb 25, 2022
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lima Corporate S.P.A.
Location	Winona Lake, IN, US
Contact	Antonia Trevisan
510(k) history	64 submissions · 64 cleared · 2011-2026

REGULATORY CONSULTANT

Consulting firm	Lima U.S.A., Inc.
Contact	Lacey Harbour

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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