

**K243826 SMR Reverse HP Shoulder System**Jul 3, 2025  
203 days to decisionK243826 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k243826/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Dec 12, 2024
Decision date	Jul 3, 2025
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lima Corporate S.P.A.</b>
Location	Winona Lake, IN, US
Contact	Marco Tallerico
510(k) history	64 submissions · 64 cleared · 2011-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Sarah Pleaugh

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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