FDA 510(k) Premarket Notification

K243826 SMR Reverse HP Shoulder System

CLEARED

Jul 3, 2025
203 days to decision

K243826 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k243826/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Sarah Pleaugh

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