FDA 510(k) Premarket Notification

K231099 SMR Hybrid Glenoid System

CLEARED

Dec 21, 2023
247 days to decision

K231099 · Product code: **MBF** · Orthopedic
Source: https://www.510kdatabase.net/k231099/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer, Uncemented (MBF)
Date received	Apr 18, 2023
Decision date	Dec 21, 2023
Days to decision	247 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	Michela Zanotto
510(k) history	64 submissions · 64 cleared · 2011-2026

REGULATORY CONSULTANT

Consulting firm	**Lima U.S.A., Inc.**
Contact	Kenneth Newman

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