FDA 510(k) Premarket Notification

K213785 SMR TT Hybrid Glenoid, SMR 3-Pegs Cemented Glenoid

CLEARED

May 13, 2022
158 days to decision

K213785 · Product code: **KWS** · Orthopedic
Source: https://www.510kdatabase.net/k213785/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Dec 6, 2021
Decision date	May 13, 2022
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Limacorporate**
Location	San Daniele Del Friuli, IT
Contact	Roberto Gabetta
Website	http://www.limacorporate.com/
510(k) history	4 submissions · 4 cleared · 2019-2025

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