FDA 510(k) Premarket Notification

K222405 Smart SPACE Shoulder Planner and 3D Positioners

CLEARED

Dec 20, 2022
133 days to decision

K222405 · Product code: **QHE** · Orthopedic
Source: https://www.510kdatabase.net/k222405/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Aug 9, 2022
Decision date	Dec 20, 2022
Days to decision	133 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	Francesca Marello
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