

K222405 Smart SPACE Shoulder Planner and 3D PositionersDec 20, 2022
133 days to decisionK222405 · 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](https://accessdata.fda.gov)

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