

K212992 LINK® Embrace Shoulder System - Reverse Configuration

Nov 18, 2021
59 days to decisionK212992 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k212992/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Sep 20, 2021
Decision date	Nov 18, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Waldemar Link GmbH & Co. KG
Location	Mchenry, IL, US
Contact	Stefanie Fuchs
510(k) history	42 submissions · 42 cleared · 1978-2025

REGULATORY CONSULTANT

Consulting firm	LinkBio Corp.
Contact	Terry Powell

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

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