

# K231445 LINK Embrace Shoulder System - Reverse Configuration

Nov 16, 2023  
182 days to decisionK231445 · Product code: PHX · Orthopedic  
Source: <https://www.510kdatabase.net/k231445/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	May 18, 2023
Decision date	Nov 16, 2023
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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

## REGULATORY CONSULTANT

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Consulting firm	<b>LinkBio Corp.</b>
Contact	Mateusz Leszczak

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

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