

## **K200368 LINK Embrace Shoulder System - Reverse Configuration**

Feb 5, 2021  
357 days to decisionK200368 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k200368/>

### **SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Feb 14, 2020
Decision date	Feb 5, 2021
Days to decision	357 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	Stephanie Fuchs
510(k) history	42 submissions · 42 cleared · 1978-2025

### **REGULATORY CONSULTANT**

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Consulting firm	<b>LinkBio Corp.</b>
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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