

K210899 LINK Embrace Shoulder System- Anatomical Configuration

Jun 21, 2021
87 days to decisionK210899 · Product code: **KWT** · Orthopedic
Source: <https://www.510kdatabase.net/k210899/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	Mar 26, 2021
Decision date	Jun 21, 2021
Days to decision	87 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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